

EXHIBIT 5

US005776161A

United States Patent [19]**Globerman**[11] **Patent Number:** **5,776,161**[45] **Date of Patent:** **Jul. 7, 1998**[54] **MEDICAL STENTS, APPARATUS AND METHOD FOR MAKING SAME**5,514,154 5/1996 Lau et al. 606/194
5,591,197 1/1997 Orth et al. 606/191[75] **Inventor:** **Oren Globerman**, Holon, Israel[73] **Assignee:** **Instent, Inc.**, Eden Prairie, Minn.[21] **Appl. No.:** **543,337**[22] **Filed:** **Oct. 16, 1995**[51] **Int. Cl.⁶** **A61M 29/00**[52] **U.S. Cl.** **606/194; 606/192; 623/1**[58] **Field of Search** 606/192, 194,
606/198, 191; 623/1, 12[56] **References Cited****U.S. PATENT DOCUMENTS**

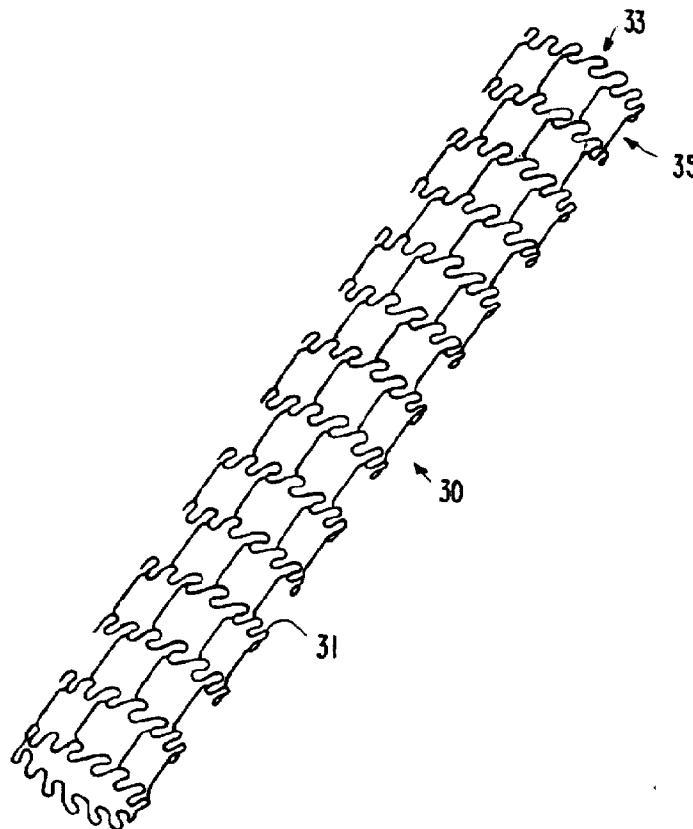
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Primary Examiner—Michael Buiz*Assistant Examiner*—Patrick W. Rasche*Attorney, Agent, or Firm*—Levisohn, Lerner, Berger & Langsam

[57]

ABSTRACT

An expandable stent and stent graft having a small initial diameter, flexibility along its longitudinal axis prior to expansion and a large expanded and rigid Local strain on the stent material is minimized, as and after the balloon is expanded. More particularly, the stent has rotation joints having minimal strain during stent expansion. The stent is substantially the same length before and after expansion and being flexible longitudinally when constrained, it is easy to locate. A method of manufacturing stents is described comprising rotation of a tube beneath a moving film, with light passing through the film onto the tube, at selected locations. A laser scanning system for stent manufacture is also disclosed.

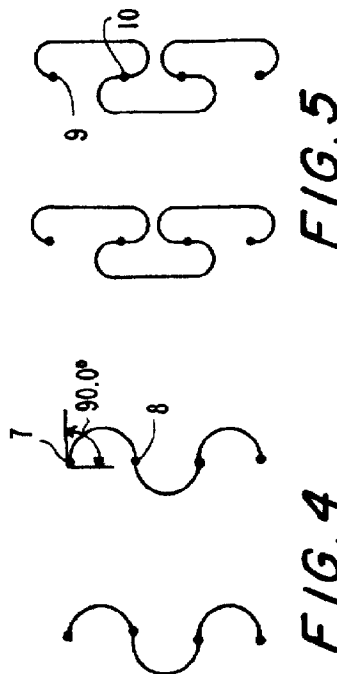
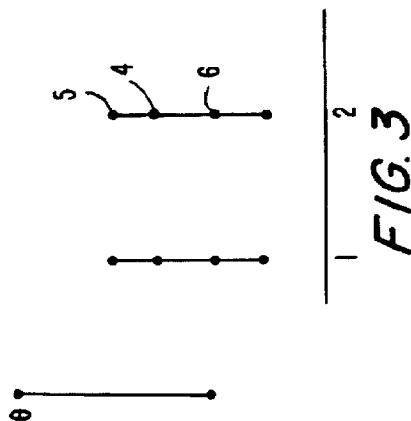
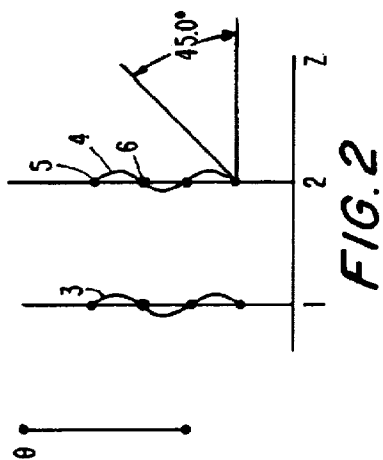
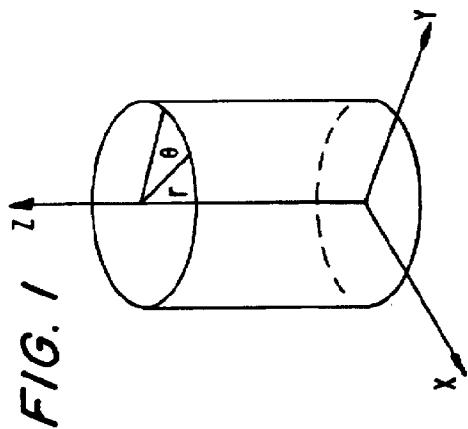
25 Claims, 12 Drawing Sheets

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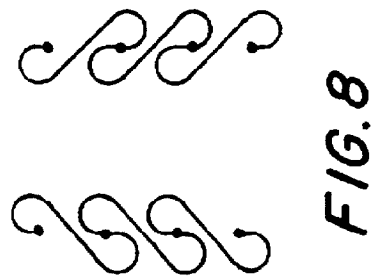
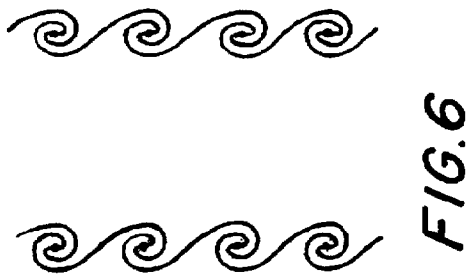
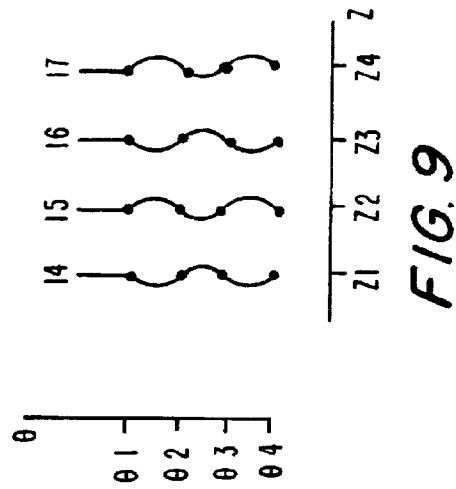
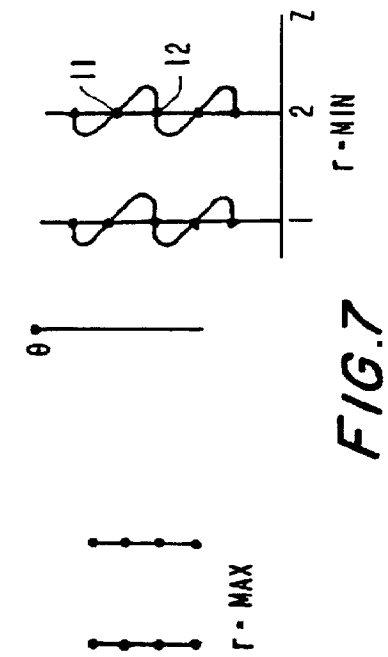


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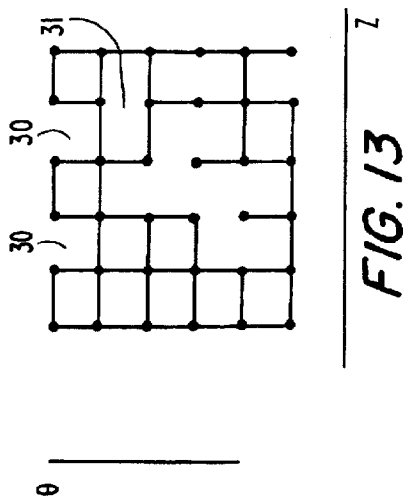
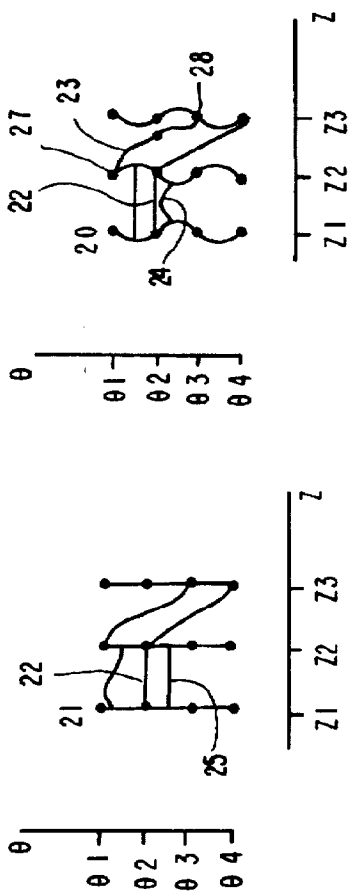
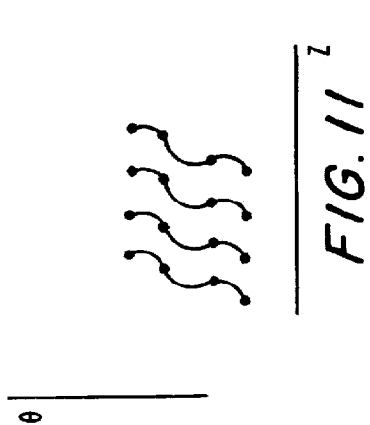


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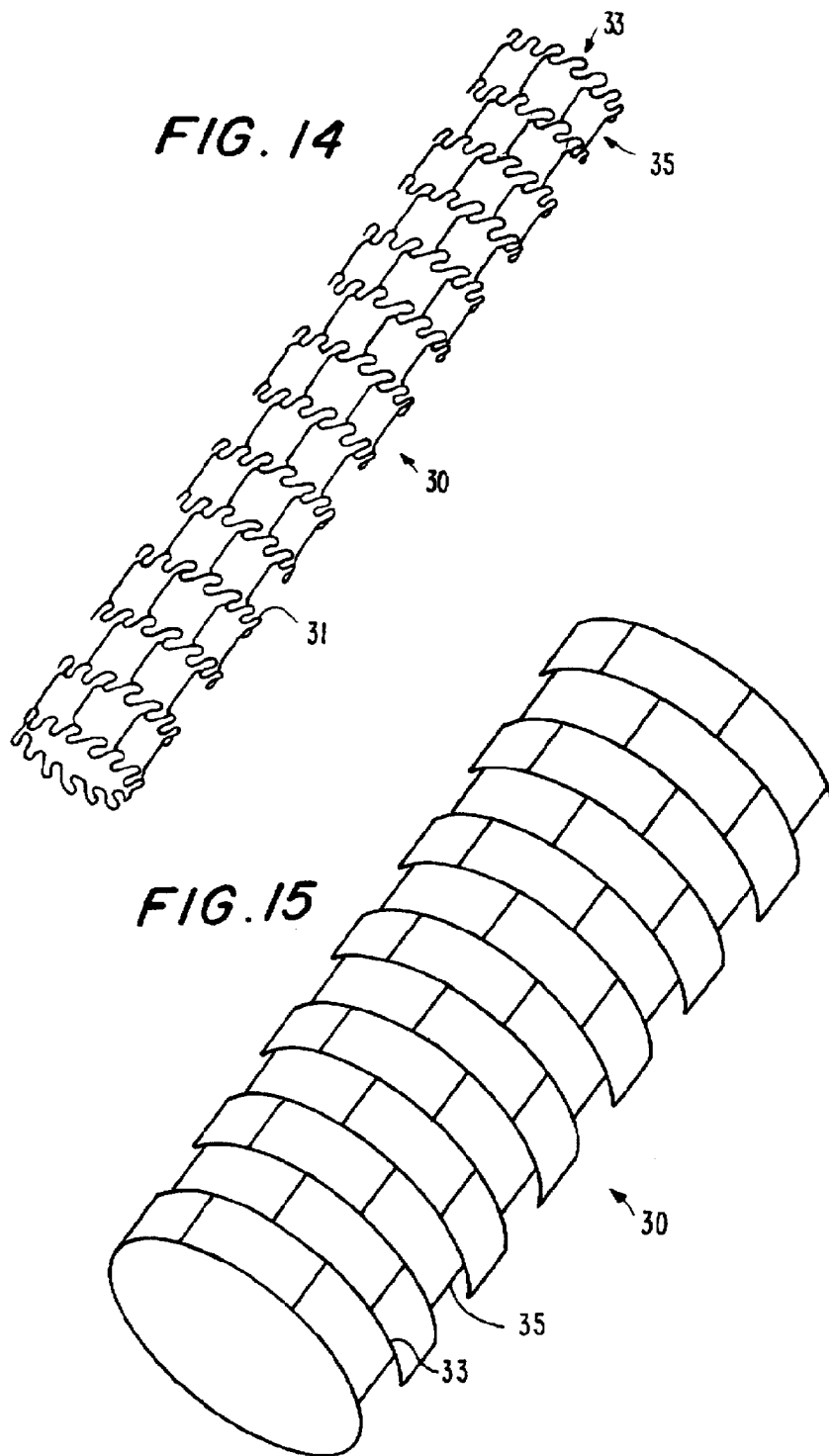


FIG. 16

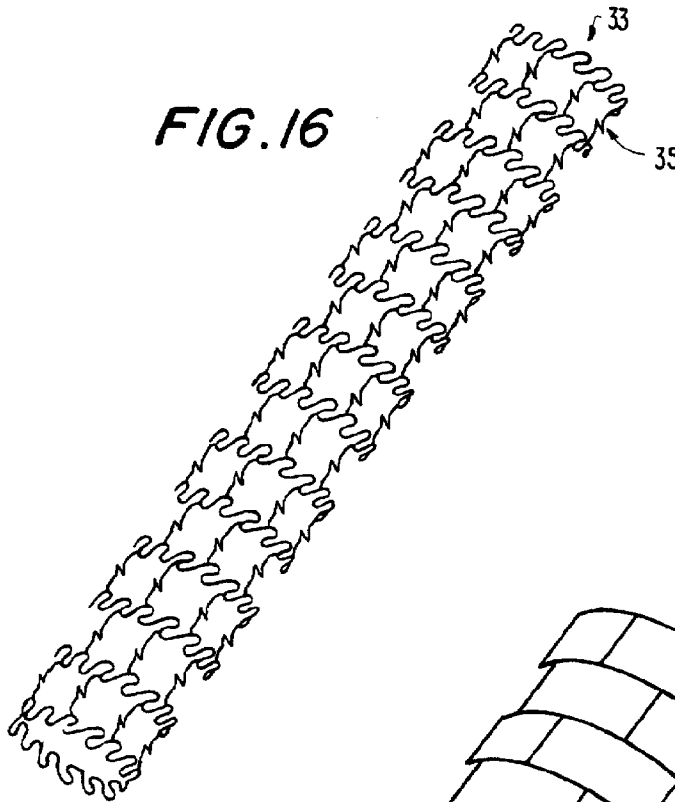
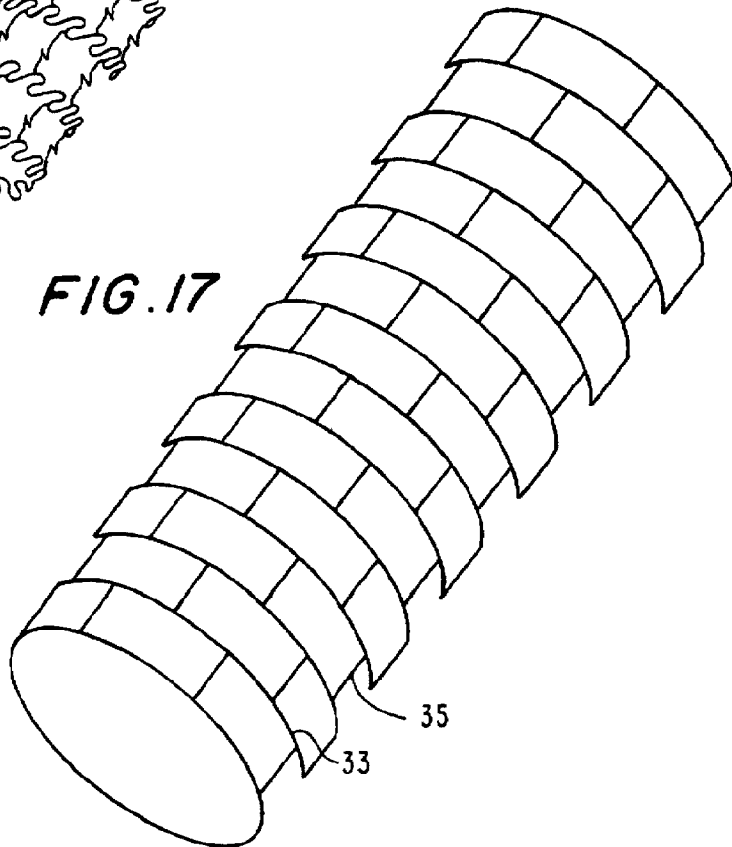


FIG. 17

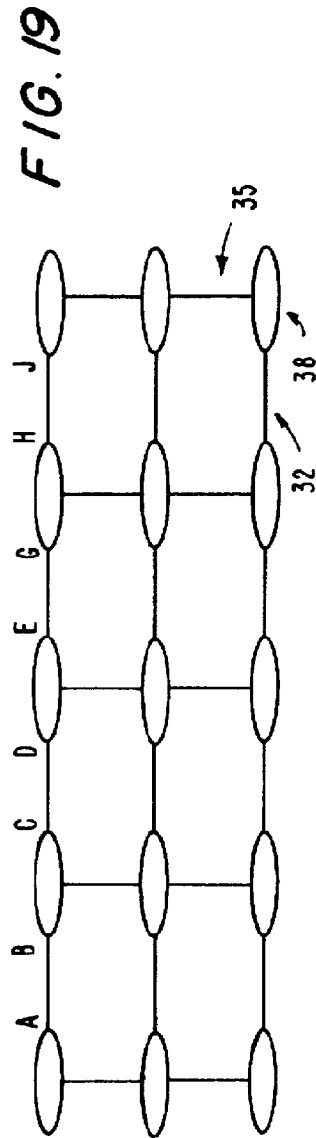
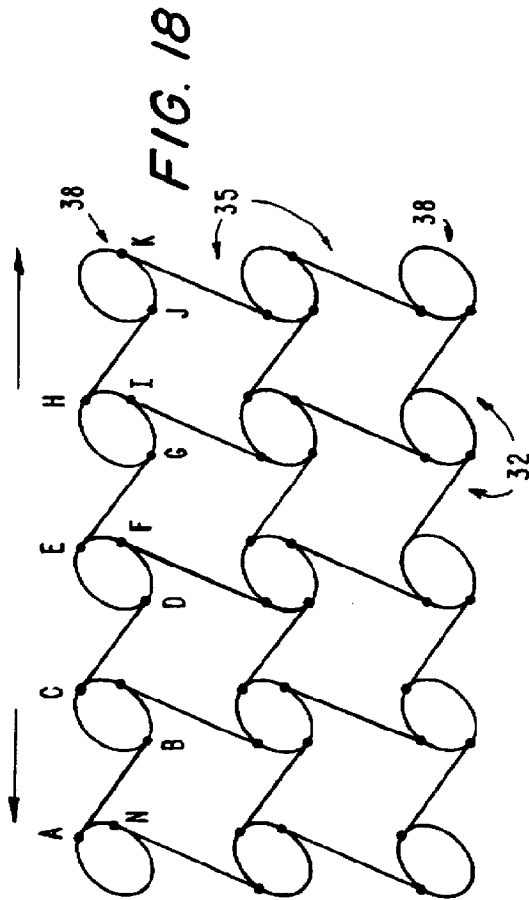


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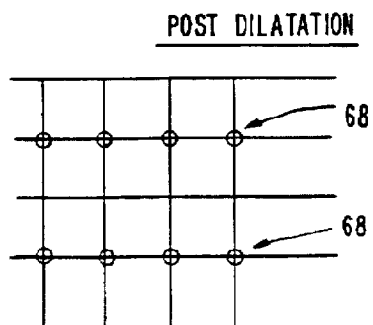
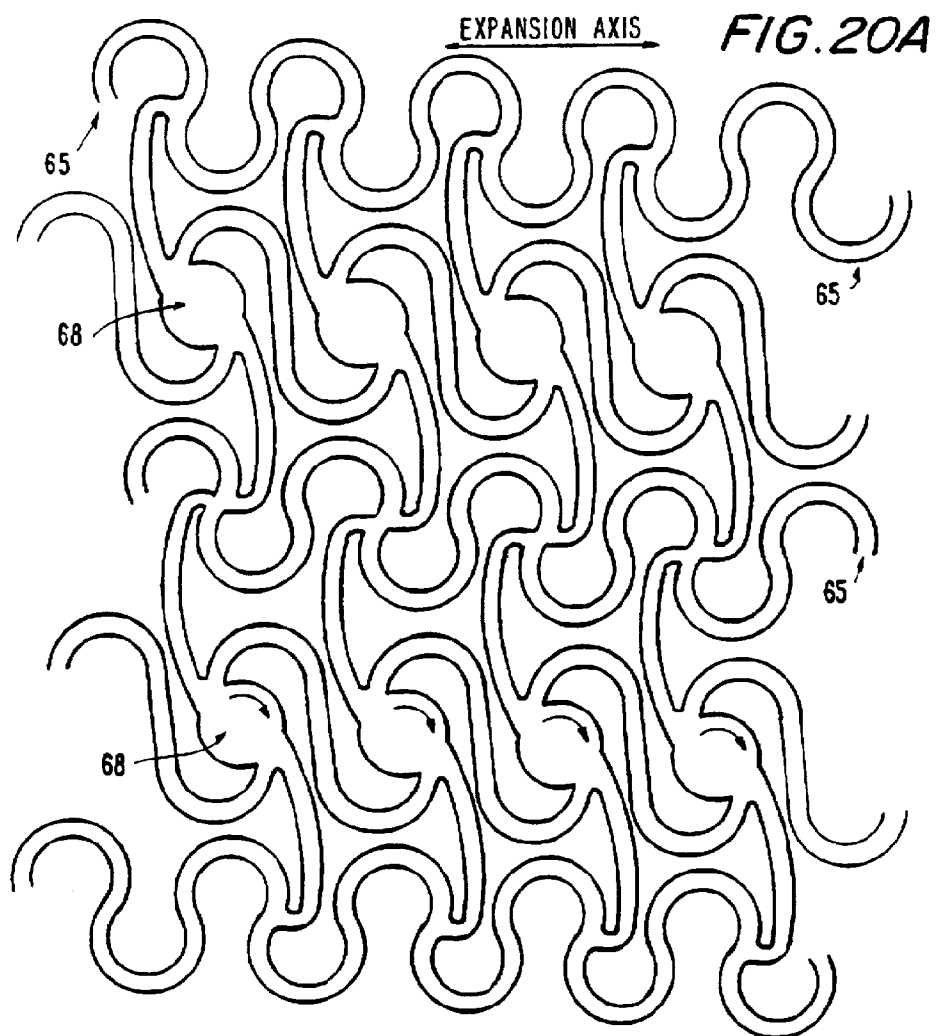


FIG. 20B

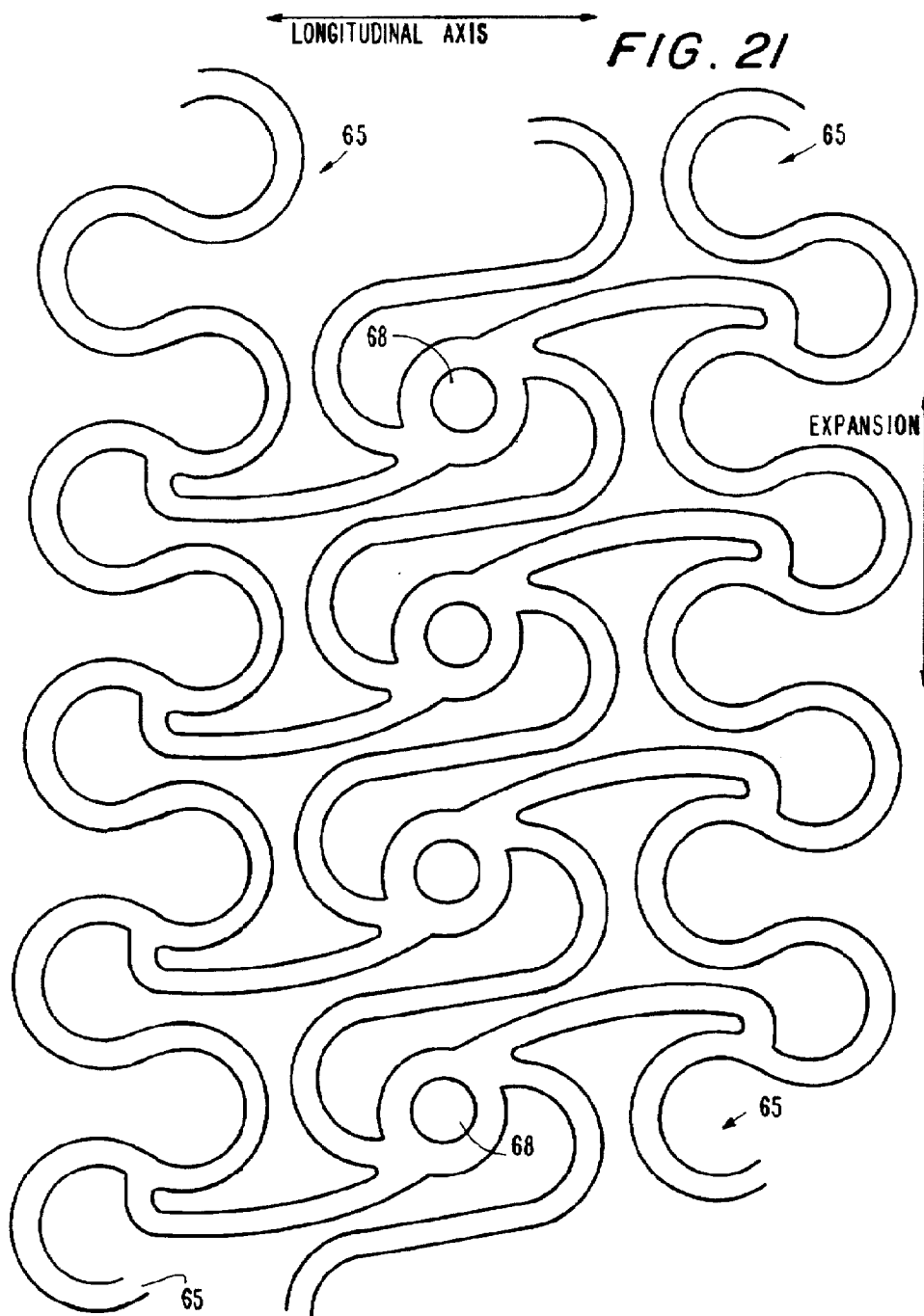
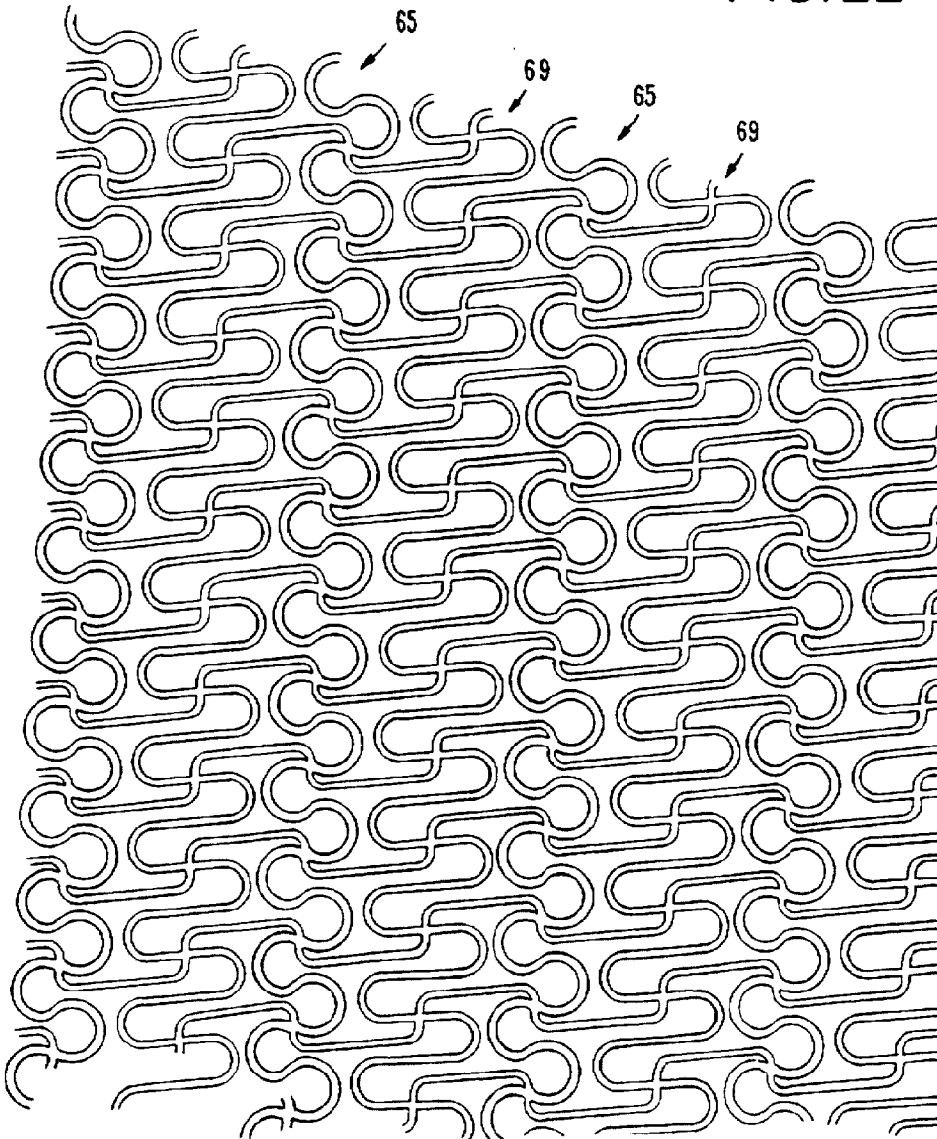


FIG. 22



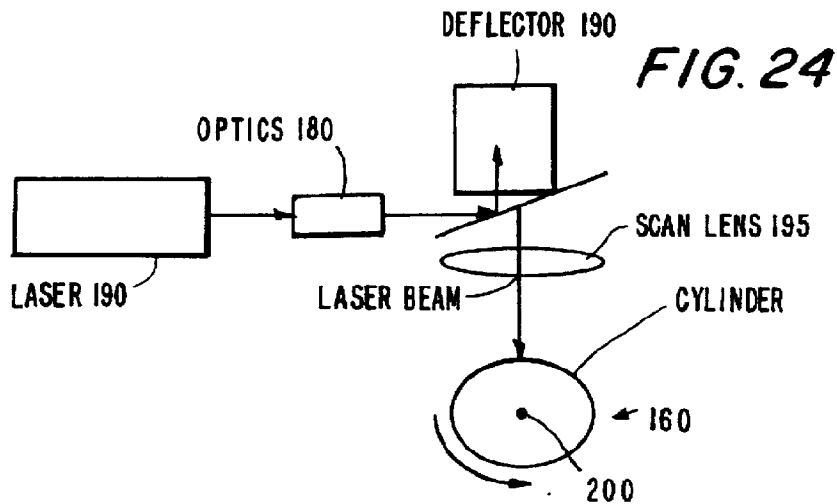
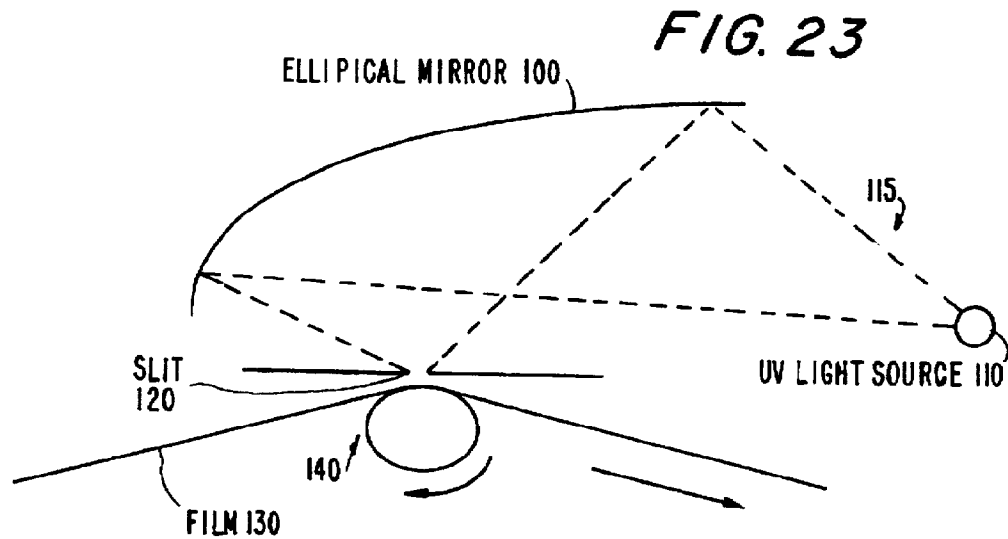
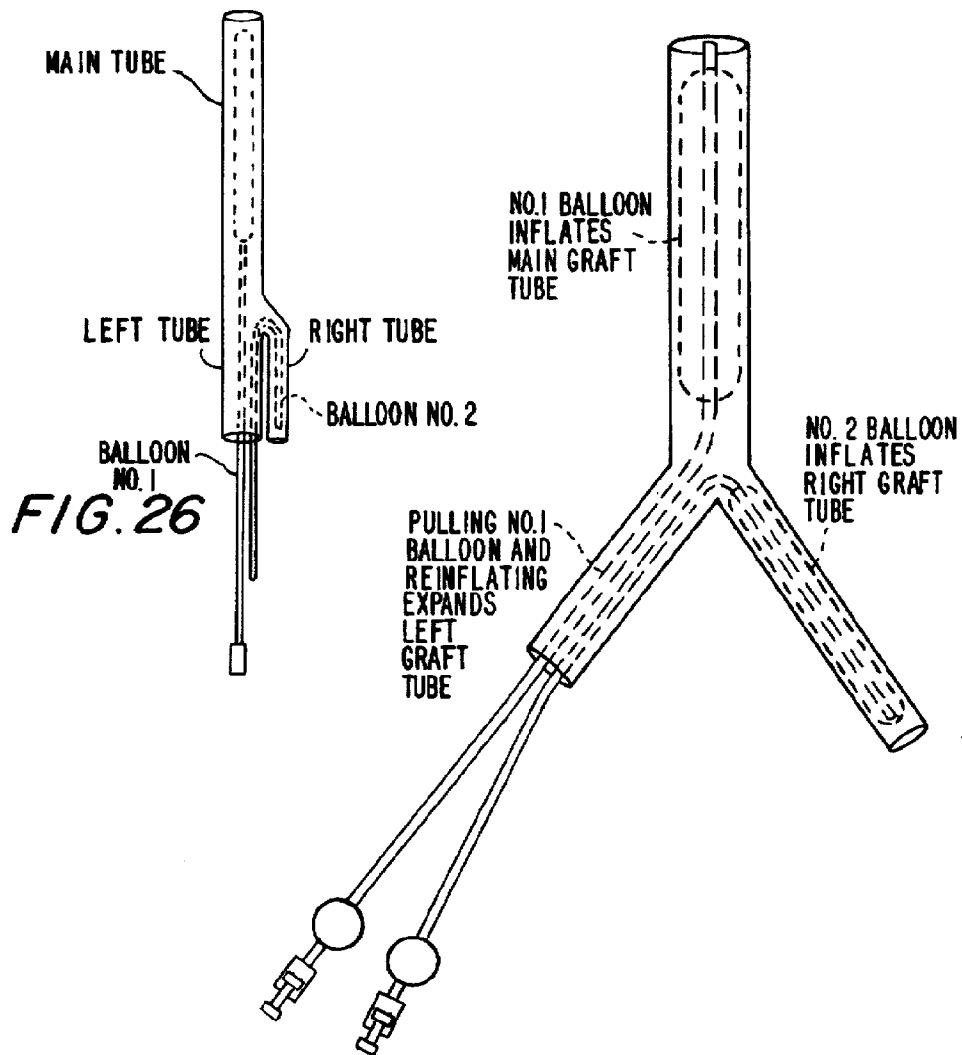


FIG. 25



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FIG. 27

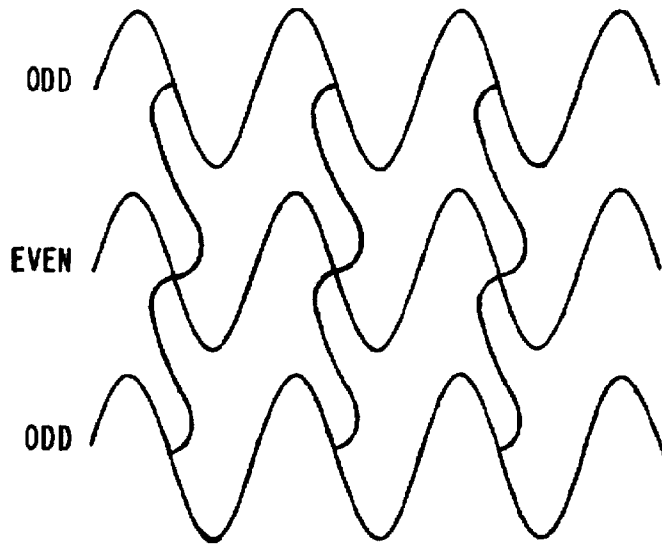
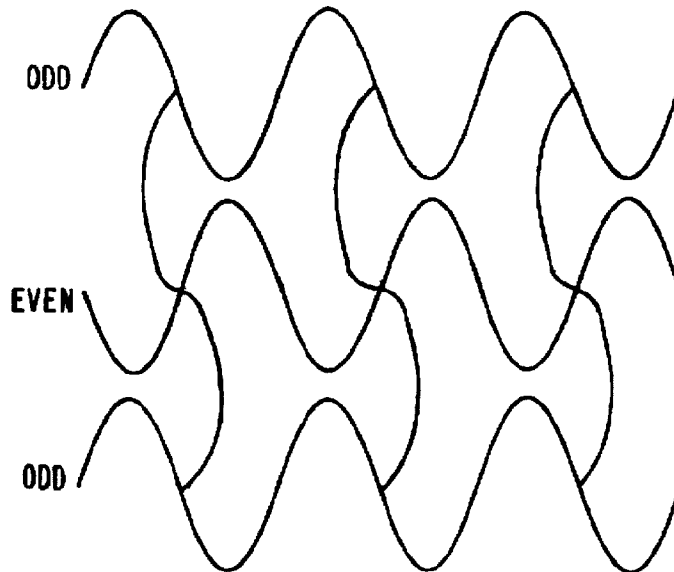


FIG. 28



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MEDICAL STENTS, APPARATUS AND METHOD FOR MAKING SAME

FIELD OF THE INVENTION

The present invention relates to an improved stent and stent graft for use in constricted body tubes, and for widening a stenosis in a body cavity such as in an artery, in the bile duct, esophagus, and so forth. The present invention also relates to stent production technology, and a method for manufacture of the improved stent device.

BACKGROUND OF THE INVENTION AND DESCRIPTION OF THE PRIOR ART

Intraluminal endovascular stenting is a method by which a prosthesis is inserted into a body tube and expanded so as to reopen a collapsed vessel wall and prevent the wall from recollapsing into the lumen. Endovascular stenting is particularly useful for arteries which are blocked or narrowed and is an alternative to surgical procedures that intend to bypass the occlusion.

Previous structures used as stents or intraluminal vascular grafts have included coiled stainless steel springs; helical wound spring coil made from shape memory alloy; expanding metal stents formed in a zig-zag pattern; diamond shaped, rectangular shaped, and other mesh and non-mesh designs. Some of the stents currently available employ a self expanding concept, whereby stent expansion is primarily achieved by removing a restraint mechanism holding the stent in a constricted configuration. Other stents in the prior art are delivered to the site by a balloon catheter system, and primarily employ balloon dilation to achieve proper stent expansion.

Problems with this variety of stents is inadequate radial force to maintain expansion; inappropriate scaffolding of tissue to the wall; pre-dilated longitudinal rigidity which negatively impacts on stent delivery; and shortening of the stent as a consequence of radial expansion. Predilation stent longitudinal rigidity is a significant shortcoming, and prevents the threading of the stent through long tortuous vessels and lesions. Shortening of the stent is also a problem, as it is important that the stent cover the entire lesion to minimize the risk of post-operative complications. Obviously, therefore, there is a need for a long yet flexible stent that will provide the appropriate scaffolding effect, will be able to track well in-curved vessels, will not shorten during radial expansion, and yet will have sufficient outward radial force to hold the artery open, even in the presence of hard calcified lesions. The stent disclosed herein overcomes these disadvantages. No stent having all of the desired features appears to exist, prior to this invention which achieves most of these properties.

As is well known, a traditional alternative to conventional vascular surgery has been percutaneous transluminal balloon angioplasty (PCTA). In this procedure, the angioplasty balloon is inflated within the stenosed artery to create, through shearing and mechanical trauma, a larger inner lumen. This process, while successful in achieving a larger lumen in most cases, can sometimes cause local tears, dissections and protrusion of plate into the lumen so that vessel blockage is caused rather than the desired vessel opening. In addition, the phenomenon of elastic recoil and intimal growth following arterial dilation often causes late restenosis (within six months) in more than about 30% of the patients undergoing the angioplasty balloon procedure. Because of the fear of the acute complication of sudden occlusion (abrupt closure), a surgical backup is needed in

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most places where PTCA is performed. This is yet another limitation of the mechanical balloon dilatation procedure.

It has been shown that stenting results in excellent acute results with adequate scaffolding of tears to the wall of the artery and with generation of a large inner lumen. This large inner lumen, initially present after stenting, has a lower restenosis rate after the procedure, as shown in the STRESS (N. Engl. J. Med. 1994; 331:L 496-501) and BENESTENT (N. Engl. J. Med. 1994; 331: 489-95) studies. While the inner lumen achieved using the self-expanding stents depends on the sizing of the stents relative to the vessel, the inner lumens that can be achieved with balloon expandable stents depend both on the size and radially expanding pressure of the balloon. The inner lumens achievable with balloon expandable stents can be further increased with further inflation of the balloon.

One of the major complications associated with stent use has been thrombosis. The problem occurs most commonly between day 2 and 6 of the implantation, but may also occur as late as 3 weeks after stenting. This complication is caused by clotting of the stent and is associated with high morbidity and mortality. It has been recently shown that the better the stent apposition against the wall and the larger the lumen is, the less likely that this complication will occur. In addition, it is very important that the stent cover the entire lesion since the existence of obstructions before or after the stent may also cause a complication.

The current balloon expandable stents have the significant limitation of relative, longitudinal rigidity during delivery, and so do not allow for a very long stent to traverse the usual curves in the artery. This longitudinal rigidity during delivery is sought to be avoided by devices taught in the patents to Wolff (U.S. Pat. No. 5,104,404) and to Pinchasik (U.S. Pat. No. 5,449,373) in which the rigid Palmaz stent sections are connected together with flexible connections. For this reason, it is required that the stent be long (to allow treatment of long lesions) and flexible upon insertion to site (to allow passage to and through tortuous locations) but yet have large radial force to unblock the vessel and excellent scaffolding so as to be able to hold the atherosclerotic material against the wall, even in bends and in hard calcified lesions. The stent should also allow for further balloon expansion if further lumen enlargement is required at particular locations.

In U.S. Pat. No. 5,104,404, Pinchasik attempts to address some of the shortcomings of the prior art by teaching the use of different connectors (articulation) between the rigid Palmaz stent segments, enabling more flexibility between the rigid parts.

It would be highly desirable, however, to have a stent having few or no longitudinally rigid parts so that it will be homogeneously flexible along its entire longitudinal axis when delivered on the catheter. Furthermore it would be extremely desirable to eliminate the longitudinal shortening of the stent during radial expansion to minimize stent misplacement.

Furthermore, in Palmaz' stents marketed by Johnson & Johnson, as well as in others, during plastic deformation of the stent (i.e. balloon expansion) the strain is concentrated at small zones. This limits the properties of the material that can be used as well as the radial force and the expansion rate. By distributing the strain over large zones, a less thick annealed material can be used to both avoid deterioration of the radial force of the stent when expanded, and to reduce the stent's constricted profile. There are obvious advantages to reduced stent thickness.

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According to the prior art method of manufacturing stents, the material is originally flat. The screen-like material is then rolled into a cylinder shape and laser welded or otherwise connected to form a tube—the weld running the length of the longitudinal axis. This is a difficult and expensive manufacturing procedure. It also leads to a potential lack of uniformity. The present invention, a new method of stent manufacture, as will be explained, results in a more uniformly expandable stent, one not having a weld line formed after mesh formation.

Patents which relate to the field of stent geometry are as follows: U.S. Pat. Nos. 5,354,309; 4,776,337; 5,356,423; 5,383,892; 5,178,618; 5,449,373; and 5,104,404.

SUMMARY OF THE INVENTION

The object of the present invention is to provide a stent which has flexibility substantially along its longitudinal axis when constrained on a catheter to allow it to easily pass through and along highly curved body vessels and fluid-carrying tubes.

It is further an object of the invention to supply the constricted stent (i.e., before balloon expansion) with a minimum diameter to ease its passage for placement through a minimal diameter vascular port as well as to enable it to enter through narrow lumens of constricted body tubes.

It is further an object of the invention to provide a stent geometry which results in a more homogenous distribution of the strain on the stent material, reducing the maximum strain on the stent when expanded so that less material can be used. Subjecting less material to the same balloon-expanding force can result in greater radial expansion. This allows both a greater expansion ratio for the stent and smaller stent wall thickness.

It is further an object of this invention to allow a stent geometry and proper material to provide additional stent diameter expansion by elongation of the stent material (such as tantalum) and not by changing the shape of the stent.

It is further an object of the invention to provide a stent which does not substantially change in length as the stent diameter is expanded during balloon inflation.

A further object of the present invention is to provide a method for fabricating stents and, in particular, the stents disclosed herein.

It is a further object of the invention to supply the stent with a graft material to be a stent graft as well as a stent graft of Y-shape for aortic aneurism.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a stent (shown as a cylinder for illustrative purposes) in cylindrical coordinates;

FIG. 2 is a partial section of a stent, showing a pair of radial rings, unconnected in the longitudinal direction (for illustration) and showing a stent before expansion, having points or dots on the rings which will rotate 45° upon expansion due to balloon inflation. (In FIGS. 21–11, the interconnections between the adjacent radial rings of the stent are not shown.). A ring of the stent resembles a lock washer, an undulating ring shape;

FIG. 3 is a partial section of a stent showing the pair of adjacent radial rings of FIG. 2, after expansion of the stent;

FIG. 4 is a partial section of a pair of radial rings of a second embodiment of a stent, without longitudinal connection (for ease of illustration) before expansion, having points or dots on the rings which will rotate 90° upon stent expansion;

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FIG. 5 is a partial section of another embodiment of a stent showing a pair of radial rings, before expansion, having points or dots on the rings which will rotate 180° upon expansion;

FIG. 6 is a partial section of a pair of radial rings of another embodiment of the stent, again, before expansion, having points or dots on the rings which will rotate 360° upon expansion;

FIG. 7 is a partial section of a pair of radial rings of another embodiment of the stent, both before (on the right side) and after (on the left side) expansion, having two types of dots or points on the rings which will rotate through angles of 45° and 90° respectively, upon expansion;

FIG. 8 shows a partial section of a pair of radial rings of another embodiment of the stent, before expansion, in which the radial rings have two types of dots or points on the rings which will rotate through angles of 45° and 180°, respectively, upon expansion;

FIG. 9 shows two pairs of radial rings of yet another embodiment of the stent, before expansion, in which adjacent rings are constructed with mirror images of each other;

FIG. 10 shows four radial rings in which neighboring rings are offset, i.e., have constructions which differ by an angle of rotation from each other. The “z” and “θ” angles are shown on the axis; the “θ” axis, corresponds to the angle “θ” illustrated in FIG. 1;

FIG. 11 shows a partial section of four rings of yet another embodiment of a stent, before expansion;

FIG. 12 shows a graphical depiction of two types of longitudinal connections between neighboring radial rings of a stent, the right side of the Figure being before stent expansion;

FIG. 13 shows a graphical representation of a section of an expanded stent which has been constructed such that some of the radial segments and some of the longitudinal connections are deliberately omitted during manufacture;

FIG. 14 is a perspective view of a stent according to the present invention with the stent in its constricted form, prior to expansion and wherein the connections between adjacent rings of the stent are straight;

FIG. 15 is a perspective view of the stent of FIG. 14 with the stent in its expanded form;

FIG. 16 is a perspective view of another embodiment of a stent in which the connections between the adjacent rings of the stent are also curved. The stent is shown in the constricted form prior to expansion;

FIG. 17 is a perspective view of the stent of FIG. 16 in its expanded form;

FIG. 18 shows an enlarged partial section of another embodiment of a stent in which the stent joints (between the adjacent rings) are circular, and the stent is in its constricted form, prior to the expansion. Individual rings are formed with the circular joints, as well;

FIG. 19 shows the portions of the stent of FIG. 18 in its expanded form. Points A, B, C, D, E, F, G, H, I, J and K have been shown on both FIGS. 18 and 19 (opposed, offset U-shapes) to illustrate relative movement and location, a consequence of stent expansion;

FIG. 20A shows a partial enlarged section of another embodiment of a stent with undulated (opposed, offset U-shapes) rings, strips or segments separating adjacent rings, and alternate rings having simple intersections between adjacent points on the same ring and circular joints between adjacent points. FIG. 20A shows the stent in a

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constricted form; FIG. 20B is a schematic representation of the stent of FIG. 20A in an expanded form;

FIGS. 21 and 22 show partial sections of a stent with undulated (opposed, offset U-shapes) radial strips or segments as in FIG. 20A, forming the rings, yet with the circular connectors being hollow. The rings are connected by longitudinal segments;

FIG. 22 shows another embodiment with undulating rings, longitudinal connectors and simple intersections;

FIG. 23 is a side elevational schematic view of a film contact imaging apparatus for stent manufacture;

FIG. 24 is a similar schematic view of a laser scanning system for stent manufacture;

FIG. 25 is a schematic representation of a Y-tube stent graft in the open position, according to the present invention;

FIG. 26 is a schematic representation of a Y-tube stent graft in the closed configuration.

FIG. 27 is an enlarged partial view of the stent of the present invention, in an embodiment where all the rings are in phase; and

FIG. 28 is an enlarged partial view of the stent of the present invention, in an embodiment where adjacent or paired rings are 180 degrees out of phase with one another. Of course, as will be appreciated from the description of the drawings and of the invention, all angles between 0 degrees and 180 degrees can be used for the lateral offset of the "peaks" and "valleys" of the adjacent rows. FIG. 28 shows that the repetitive "peaks" and "valleys" of adjacent rings are offset by about 150 to 160 degrees.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a novel stent construction. The stent geometry allows both longitudinal flexibility of the stent when the stent is constricted to its initial narrow diameter for threading through the body vessel, and maximum rigidity, after the stent is expanded to its final large diameter, for supporting the body vessel wall. The geometry of the stent is further designed to allow the stent to remain substantially the same length before and after expansion and even zero strain on the connection points.

Moreover, as will be described below, the stent geometry allows a substantially homogeneous distribution of strain on the stent material. This allows for less local strain (e.g. on the connection points securing neighboring radial rings of the stent to longitudinal segments and forming the rings themselves), and thus a smaller stent profile is achieved. It aids stent delivery, inside body tubes. Also, the less material used for the stent, the less rejection of the body to the foreign material. This geometry of the stent also allows a further diameter expansion by material stretching such as tantalum which allows up to about 40% elongation. The stent's further expansion is better achieved by the homogeneous distribution of stress, a result of the new geometry.

FIG. 1 shows a cylindrical stent with orthogonal cylindrical coordinates (R, θ , Z). Coordinate Z corresponds to the longitudinal central axis of the stent. When Z=0, the stent's longitudinal end is described. The stent length, its longitudinal axis, is Z. Radius r refers to the radius of the stent from the longitudinal axis of the stent to the outer circumference of the stent. Radius r, of course, changes with stent dilation during deployment of the balloon or other expansion of the stent radius by another mechanism (e.g., memory metal). As shown in FIG. 14, the stent 30, in its constricted state (i.e. before expansion), is a hollow cylinder, or is tube-like. The

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hollow cylinder has windings 31 on its surface joined together at points to form the radial rings. The stent has longitudinal flexibility, when in its constricted diameter, and allows for radial expansion. As shown in FIG. 15, the stent 30, in its expanded state, has the radial rings opened, the windings uncurl from their constricted to their expanded state, providing a larger radius r for the hollow cylinder of the stent construction.

FIG. 2 shows adjacent radial rings (1) and (2) of a stent. In the Figure (and in all of FIGS. 2-11) each ring is shown without the longitudinal connections which are provided between adjacent rings. The longitudinal connections are shown, for example, in FIGS. 14-16. Radial rings (1) and (2) are each originally, i.e., before expansion, curved, with the curves of the rings crossing the Z= constant axis of the ring. Each curved ring has dots or points (e.g. dot or point (3) on ring 1, and dots or points (4), (5) and (6) on ring 2, on its curves. During outward expansion of the stent, dots (5) and (6) rotate. During the rotation of the dots, no deformation occurs in the dots. During expansion, dot (5) rotates in a 45° angle clockwise manner and dot (6) rotates in a 45° angle counterclockwise manner, thereby resulting in stent geometry shown in FIG. 3.

FIG. 3 shows two radial rings 1 and 2 of FIG. 2 after maximal stent diameter expansion. Although the connections on the longitudinal axis are not shown in the Figure, the resulting shape of the connected radial rings, after maximal expansion, is a cylindrical mesh of rectangular boxes (similar to screening material). A hollow cylinder of rectangular boxes is formed. The rectangular mesh can be seen by reference to FIG. 15.

As shown in FIGS. 4, 5 and 6, stents are depicted formed of rings 1 and 2 with dot rotation angles of 90°, 180°, and 360°, respectively, (and by the same principle, any intermediate angle) thereby achieving different levels of radial expansion.

In FIG. 7, the angle of rotation of the rotating dots is 45° clockwise (11) and 90° counterclockwise (for connecting dot 12).

In FIG. 9, it is shown that, in addition to achieving rotation around rotation dots or points at any radial line (Z1, Z2, . . .), it is also possible to rotate each ring in the opposite direction of rotation of its neighbor ring, i.e. like mirror images. Dots (14) and (16) will rotate counterclockwise while dots (15) and (17) will rotate clockwise. Again, flexibility of stent design is achieved.

In FIG. 10, a stent design is shown (four rings without ring interconnects for ease of illustration), as in FIG. 2, but having an angle of rotation or offset between the radial rings along the stent's longitudinal axis Z. FIG. 27 shows an embodiment of the invention where adjacent rings have their "peaks" and "valleys" in phase with one another while FIG. 28 shows an alternate embodiment of the invention where the rings are arranged in pairs with each ring of the pair is the mirror image of the other ring of the pair, i.e., the "peaks" and "valleys" of the rings are 180 degrees out of phase. Of course, according to the present invention, the offset between adjacent pairs of rings can incrementally vary from a low of 0 degrees, as shown in FIG. 27 to a high of 180 degrees, as shown in FIG. 28.

FIG. 11 shows, instead of having close radial loops as in FIG. 2-10, the present invention can also be practiced with a coil shape on which all rotation dots will be on the line that Z=K \times 0.

In FIG. 12, ring 20 is circumferentially longer than the distance between two rings Z1 and Z2 (distance between

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adjacent rings), and has shape 21 left side of FIG. 12) after stent expansion, leaving the stent length substantially unchanged. Longitudinal connector 22, whose length is equal to the distance between the two rings, does not deform during stent expansion. Connection 24 is a curved shape before stent expansion, and changes to a straight line 25 after stent expansion. The longitudinal connections can be between two dots (27 and 28) that are not necessarily placed along a line that is parallel to the Z axis.

FIG. 13 shows that for longitudinal flexibility (important for stent deployment to the site) segments of longitudinal connectors 30 and/or sections of the rings 31, can be selectively omitted for some parts of the stent.

FIGS. 14 and 16 show two embodiments of the stents, in accordance with the present invention, each in a constricted configuration. As shown, the radial rings 33 are connected with longitudinal connectors 35. In FIG. 14, the longitudinal connectors are straight (both before and after expansion), while in FIG. 16, the longitudinal connectors are curved (before expansion). FIG. 15 shows the stent 30 of FIG. 14 in an expanded configuration, after inflation by a balloon. FIG. 17 (not to scale) similarly depicts the expanded configuration of the stent of FIG. 16. As can be seen from the Figures, expansion of the stent allows the flexible, constricted configurations to be transformed into a cylinder comprised of substantially rigid rectangular grid geometry. The expanded stent is in the form a hollow tube. Consequently, the stent can be threaded through a body vessel in a flexible, constricted state, and subsequently expanded into a substantially rigid, expanded state for scaffolding against the body vessel wall.

FIGS. 18 and 19 show an embodiment of the stent where joints 38 (between adjacent rings and also forming the rings from straight segments) are circular rather than single connecting dots or points. As shown in the Figures, ring segments 32 (the arrows at the top of the Figure show the direction of stent expansion) and longitudinal connectors 35 are connected at circle joints 38. FIG. 18 shows the stent in a constricted configuration, prior to expansion, while FIG. 19 shows the stent after expansion. Points A-K represent connection points at which the radial ring segments 32 and longitudinal connectors 35 meet the joints 38. Comparing FIGS. 18 and 19, expansion of the stent from a constricted to an expanded configuration causes rotation of the connection points A-K to yield a rectangle-like mesh, in which the corners of the rectangles are occupied by the circular joints. Of course, as discussed, the mesh is in the basic hollow cylinder shape.

FIGS. 20A and B, 21 and 22 show three embodiments of the stent with undulated or highly curved radially oriented segments 65. In this embodiment, the undulations are opposed, offset U-shapes. Again, the direction of stent, radial expansion is shown on the Figures. FIGS. 20A and 20B, as well as 21 show two differing embodiments of circular or extended joints 68 (FIG. 21 shows hollow circle joints), while FIG. 22 shows a joint 69 which is a point-like intersection of stent ring segments and longitudinal elements. In these embodiments, stent expansion is achieved by rotation of the joints 68 and 69, and by consequent straightening of the undulated or highly curved, radially oriented segments 65. These embodiments allow excellent radial force and tissue scaffolding with minimal shortening along the stent's longitudinal axis. They also allow substantially homogeneous distribution of stress during expansion, with minimal stress and strain on the joints. FIG. 22 shows that every other ring is similar in geometry and thickness to every other ring with adjacent rings having different geom-

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etries and material thickness. Of course, the rings of the same geometry and material thickness can either be in phase, with its "peaks" and "valleys" or offset up to about 180 degrees, as shown in FIGS. 27 and 28.

In addition to the improvements provided by the new stent geometry described herein, use of a material such as tantalum can be particularly advantageous. Elongation of tantalum by applying radial expanding balloon pressure can achieve up to a 40% elongation of the stent material. Thus, this elongation of the stent material itself is in addition to the stent radial dilation which can be achieved from expansion of the novel stent by balloon expansion.

As shown in the drawings, the rotation points of the present stents enable large stent expansion, without creating high stress concentration on the connecting points of the stent. This is a significant improvement over both the Palmaz stent and the Pinchanskik and Wolff stents of the prior art, in which stress concentration, followed by fatigue and corrosion, at any point, is a potential problem.

Similarly, it is also shown from the descriptions and the Figures that the stent is flexible, longitudinally, when constricted to a small diameter, and becomes stiff, only after expansion. This is also an important improvement over the prior art, as the present stent is not composed of alternating, rigid and articulated components, joined together, but rather is integrally constructed as a single flexible stent, having a long length, and having the ability to bend, homogeneously, along its longitudinal axis when in its constricted form.

Fabrication of the stents shown in FIGS. 1-22 can be accomplished in numerous manners. Two new methods and systems for manufacture of the stents are however, shown in FIGS. 23 and 24.

One current method for fabrication of a patterned etched cylinder is to form a wire mesh from a flat planar surface and then to fuse its two opposite edges to create a cylinder. That method, however, suffers a basic disadvantage in that the presence of the fusing line creates a weakened area along the longitudinal axis of the stent, which is potentially subject to fatigue and breakage. It would be preferable for the stent to be formed from a more uniform piece of material to avoid this potential problem.

According to the present invention, there is, therefore, provided two novel alternative methods for imaging the desired pattern i.e., the location of points, undulating connectors, ring and connecting segments, etc. onto a cylinder, without the need of fusing into a cylinder after forming of the design. Either a film contact imaging method or a laser scanning system can be used to accomplish this objective.

As shown in FIG. 23, a film contact imaging method is constructed using an elliptical mirror 100 which reflects ultraviolet light from an ultraviolet light source 110. The ultraviolet light source is located at one focal point of the elliptical mirror 100 and illuminates through a slit or narrow aperture 120 (which eliminates scattered light). Slit or aperture 120 is located at the other focal point of the elliptical mirror to allow for high density power illumination from the ultraviolet source. Rays of ultraviolet light 115 are thus reflected off of elliptical mirror 100 to pass through slit or aperture 120 and onto a moving film 130. Slit 120 extends parallel to the longitudinal axis of hollow tube or cylinder 140. Film 140 carries the design sought to be provided to the tube or cylinder 140.

Film 130 is in contact with hollow cylinder 140. FIG. 22 shows a drawing of the photolithography film for the stent production, according to the method of the present inven-

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tion. Hollow cylinder 140 is material which is fabricated into the stent of the present invention. Film 130 serves as a mask or template, being transparent to ultraviolet light in some areas and opaque to ultraviolet in others in the predefined stent pattern. Cylinder 140 is coated with an appropriate material (a photoresist) for a photo-etching process. As ultraviolet light 115 is transmitted onto film 130 through slit 120, film 130 moves past cylinder 140 while the cylinder 140 rotates. The rotation of the cylinder 140 is correlated with the movement of the film 130 to appropriately image the pattern on the film around and onto the cylinder 140. As a result, ultraviolet light 115 passing through UV-transparent portions of the film template will strike the cylinder 140 in the desired pattern to photoetch the appropriate configuration onto cylinder 140. An acid treatment is then used to remove the areas which were struck by the UV light. In general, the chemical aspects of the system are similar to that used in the manufacture of computer chips i.e., photoresist, masking, acid, etc.

It should be pointed out that variations on this design can, of course, be accomplished by those of ordinary skill in the art. For example, in the presence of a sufficiently high powered light source, usage of an elliptical mirror is not essential.

As shown in FIG. 24, a second method which can be used for the fabrication of stents is a laser scanning system. The system consists of a cylinder or tube 160 to be etched, a laser 170, the laser optics 180 (containing beam components and modulator), and a dynamic deflector 190 (such as a rotating mirror, a polygon, or any other known scanning deflector). The system is based upon a well-known flat bed scanning system. Cylinder 160 is coated with a photoresist, or material suitable for photoetching. A laser 170 is selected of the appropriate power and wavelength suitable for stimulating the photoresist in use. For example, for an ablation method, the laser can be a high powered IR laser diode; for a photoresist sensitive to visible light, the laser can be a laser in the visible range or for a conventional UV photoresist, an Eximer laser or third (or higher) harmonic generation Nd:YAG/Nd:YLF laser can be used. The laser beam is shaped by an appropriate optical system, and modulated by direct modulation in the case of an IR laser diode, with AOM (an Acoustic Optical Modulator) in the case of a CW laser in the visible, or by a vibrating mirror in the case of a UV laser.

The laser beam from laser 170 hits a deflector device 190 which can be a rotating mirror, a polygon mirror, or other known scanning device. The beam emerges from the deflector, passing through a scan lens 195 and focussed on the cylinder 160. The cylinder, coated with a photoresist, rotates about its longitudinal axis 200 at a constant angular velocity, while the beam scans back and forth. The modulation of the laser beam allows writing a computer imaging file directly on the cylinder without the need of intermediate media (e.g. film). The laser scanning velocity is correlated to the cylinder angular velocity, and is determined by the energy required for exposure of the photoresist.

FIGS. 25 and 26 relate to use of the present invention as a stent graft. This is a stent over which a cloth sleeve is positioned to prevent blood from going through the stent wall or for having better support of the vessel wall. As a particular embodiment, the stent graft is in a Y-shape for the treatment of aortic aneurysm, near the aortic bifurcation. In such cases, simple tube stent grafts tend to migrate downwardly. In the Y-shape of the present invention, however, the stent is supported on the bifurcation and thus it cannot migrate from the site. A method of percutaneous insertion of

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this Y-stent graft is shown in the drawing. As shown in the drawings, the main tube integral with a right and a left tube, thereby forming the Y-shape stent graft. A first balloon passes from the left tube into the main tube while a second balloon passes into the right tube. During deployment, the right tube moves flexibly to the right. The second step of deployment contemplates the pulling of the entirety of the stent graft so that it is located and fixed to the aortic bifurcation. Then inflation of balloon No. 1 for the main tube is accomplished. Then balloon No. 2 is inflated in the right tube. Then balloon No. 1 is pulled and reinflated followed by a withdrawal of balloons. FIG. 25 shows the Y-shaped tube stent graft in its open or expanded configuration. Balloon No. 1 is shown inflated and located in the main graft tube. Balloon No. 2 is shown in the right graft tube. Pulling balloon No. 1 and reinflating the same expands the left graft tube.

Having described this invention with regard to specific embodiments, it is to be understood that the description is not meant as a limitation since further variations or modifications may be apparent or may suggest themselves to those skilled in the art. It is intended that the present application cover such variations and modifications as fall within the scope of the appended claims.

I claim:

1. A medical stent, comprising:

at least two radial rings, each of said rings being curved into peaks and valleys, and further having windings, each of said rings having both a constricted state and an expanded state corresponding to the constricted and expanded state of said windings of said stent, said constricted state being a state of said rings in which said windings are curled in shape, said expanded state being a state of said rings in which said windings are straightened such that each of said rings becomes substantially circular and of greater diameter than said ring in said constricted state; and,

longitudinal connectors, said longitudinal connectors being connected to said radial rings at rotatable joints, each of said rotatable joints being located approximately midway between the tops of said peaks and the bottoms of said valleys, said longitudinal connectors connecting said radial rings to form said stent in a cylindrical shape, said stent being flexible along substantially its entire longitudinal axis when said stent is in said constricted state, said stent being substantially rigid when said stent is expanded to said expanded state, and said stent being at least substantially the same length whether said stent is in said constricted state or in said expanded state.

2. A medical stent as claimed in claim 1, in which said rotatable joints are substantially larger than direct connections between said longitudinal connectors and said radial rings.

3. A medical stent as claimed in claim 1, wherein said stent is expandable by a balloon catheter.

4. A medical stent as claimed in claim 1, wherein said rings have points on said windings, said points rotating forty-five (45) degrees upon expansion of said rings from said constricted state to said expanded state.

5. A medical stent as claimed in claim 1, wherein said rings have points on said windings, said points rotating ninety (90) degrees upon expansion of said rings from said constricted state to said expanded state.

6. A medical stent as claimed in claim 1, wherein said rings have points on said windings, said points rotating one hundred and eighty (180) degrees upon expansion of said rings from said constricted state to said expanded state.

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7. A medical stent as claimed in claim 1, wherein said rings have points on said windings, said points rotating three hundred and sixty (360) degrees upon expansion of said rings from said constricted state to said expanded state.

8. A medical stent as claimed in claim 1, wherein said rings have at least two points on said windings, at least one of said points rotating forty-five (45) degrees in a first direction and at least one of said points on said same ring rotating ninety (90) degrees in a direction opposite to said first direction.

9. A medical stent as claimed in claim 1, wherein said stent comprises coupled pairs of adjacent rings, each of said pairs comprising a first ring and a second ring, the winding of said first ring in said pair being the mirror image of the winding of said second ring in said pair about a plane located between said coupled pairs of adjacent rings.

10. A medical stent as claimed in claim 1, wherein said longitudinal connectors are substantially straight when said stent is in said constricted state.

11. A medical stent as claimed in claim 1, wherein said longitudinal connectors are substantially straight both when said stent is in said constricted state and when said stent is in said expanded state.

12. A medical stent as claimed in claim 1, wherein said longitudinal connectors are curved when said stent is in said constricted state, and become straight when said stent expands into said expanded state.

13. A medical stent as claimed in claim 1, wherein all of said rings are not fully circular as a consequence of at least one segment of at least one of said rings being omitted.

14. A medical stent as claimed in claim 1, wherein the shape of said stent in said expanded state is a hollow cylinder of substantially rigid rectangular mesh.

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15. A medical stent as claimed in claim 1, wherein said rotatable joints are circular.

16. A medical stent as claimed in claim 1, wherein said rotatable joints are circular and hollow.

17. A medical stent as claimed in claim 1, wherein at least some of said rings comprise undulating segments.

18. A medical stent as claimed in claim 17, wherein said undulating segments are opposed and radially offset U-shapes.

19. A medical stent as claimed in claim 1, wherein at least some of said longitudinal connectors comprise undulating segments.

20. A medical stent as claimed in claim 19, wherein said undulating segments are opposed and circumferentially offset U-shapes.

21. A medical stent as claimed in claim 1, wherein said rings comprise at least a first ring and a second ring, and wherein said peaks and said valleys of said first ring are radially offset with respect to said peaks and said valleys of said second ring by greater than 0 to about 180 degrees.

22. A medical stent as claimed in claim 1, in which at least part of said stent is comprised of tantalum.

23. A medical stent as claimed in claim 1, wherein radial expansion of said rings can be accomplished, at least in part, by mechanical strain.

24. A medical stent as claimed in claim 1 wherein radial expansion of said rings can be accomplished by both uncurling of said windings and mechanical strain.

25. A medical stent as claimed in claim 1 comprising a Y-shaped stent graft.

* * * * *

EXHIBIT 6



US006203569B1

(12) **United States Patent**
Wijay

(10) Patent No.: **US 6,203,569 B1**
(45) Date of Patent: ***Mar. 20, 2001**

(54) **FLEXIBLE STENT**

(List continued on next page.)

(76) Inventor: **Bandula Wijay**, 1903 Carriage Creek Dr., Friendswood, TX (US) 77546

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

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(21) Appl. No.: **08/883,801**

(22) Filed: **Jun. 27, 1997**

Related U.S. Application Data

(63) Continuation of application No. 08/582,657, filed on Jan. 4, 1996.

(51) Int. Cl.⁷ **A61F 2/06**

(52) U.S. Cl. **623/1.15; 623/1.16; 623/1.17**

(58) Field of Search **623/1, 11, 12, 623/1.15, 1.16, 1.17**

Primary Examiner—David J. Isabella

Assistant Examiner—Choon P. Koh

(74) Attorney, Agent, or Firm—Duane, Morris & Heckscher LLP

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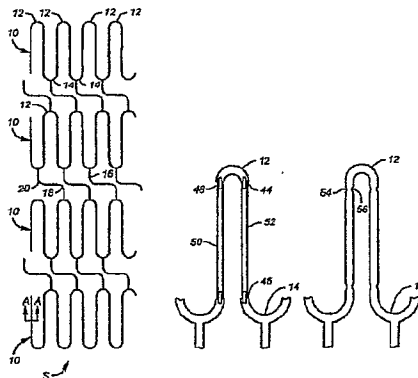
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(57) **ABSTRACT**

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossrics that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

26 Claims, 4 Drawing Sheets



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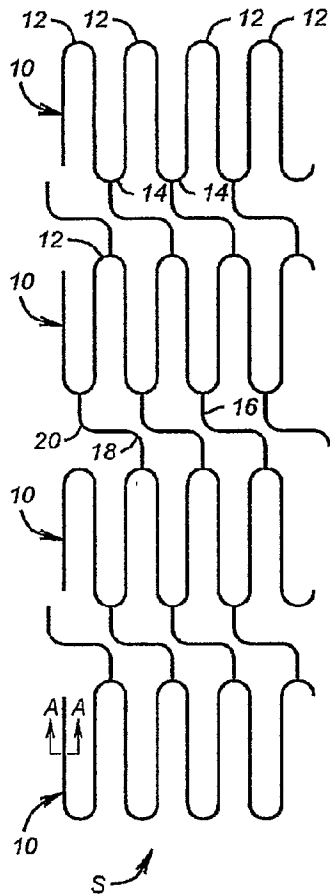


FIG. 1

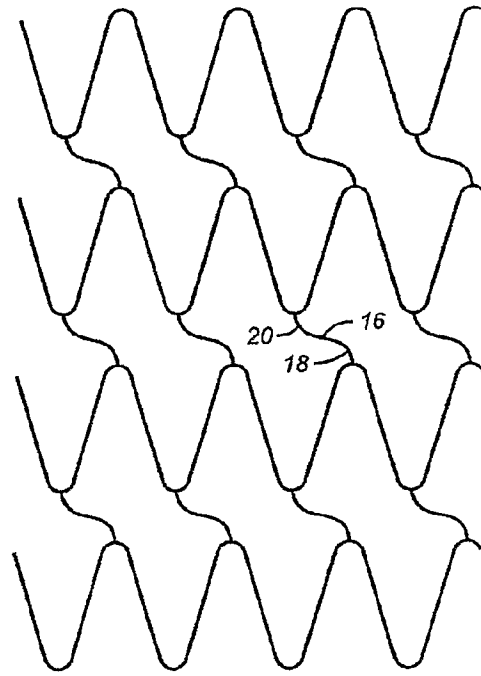


FIG. 2

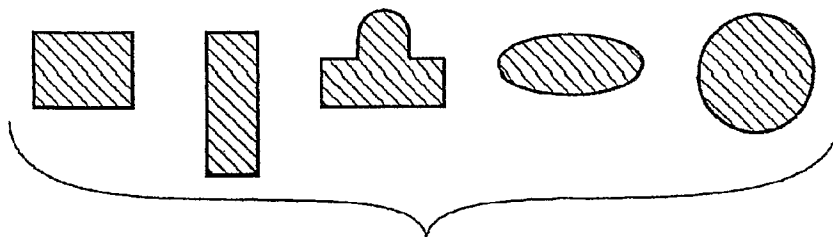


FIG. 3

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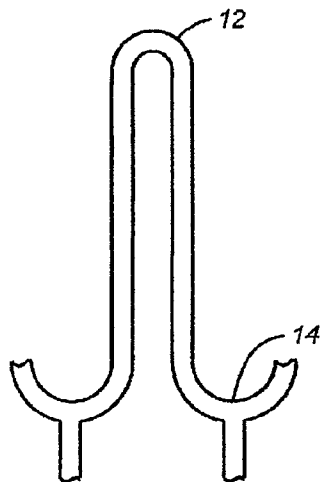


FIG. 4

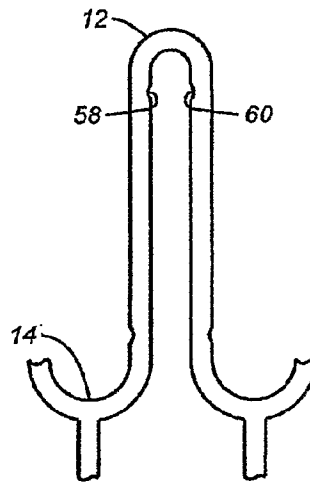


FIG. 5

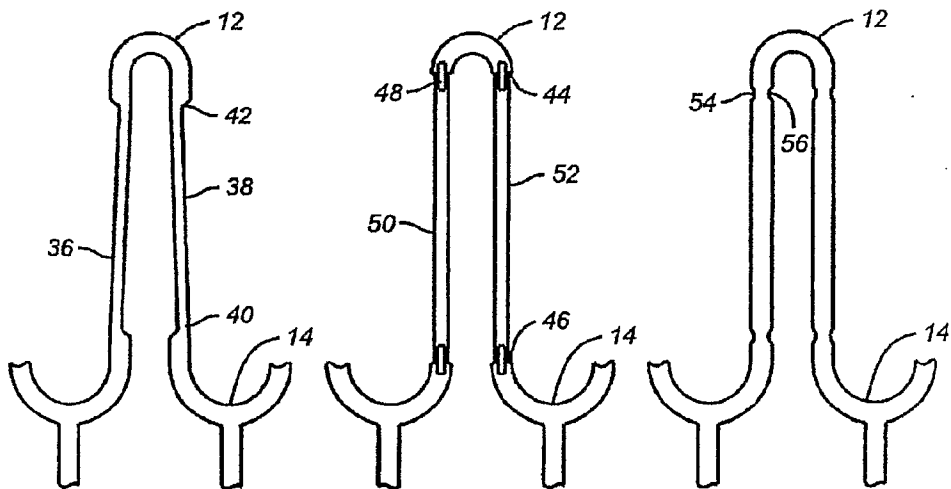


FIG. 6

FIG. 7

FIG. 8

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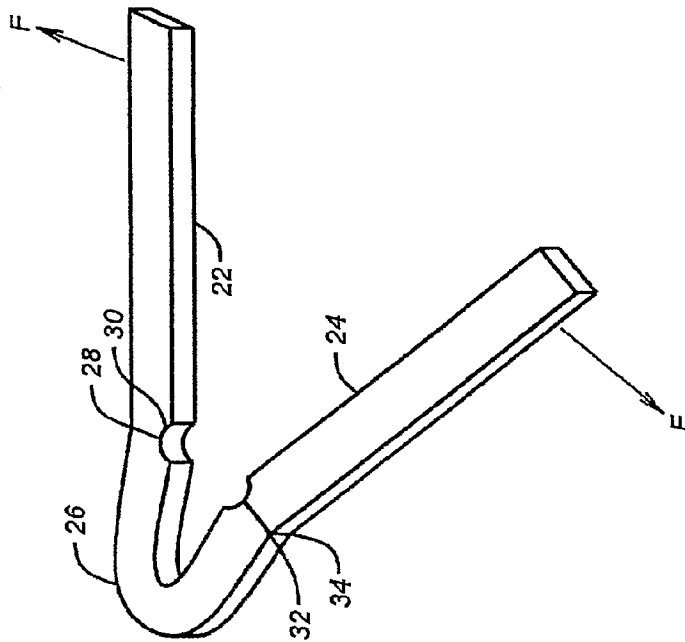


FIG. 10

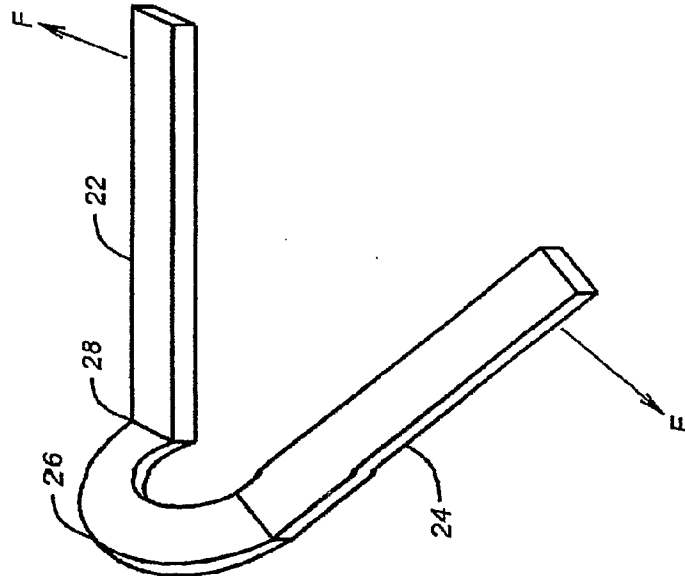


FIG. 9

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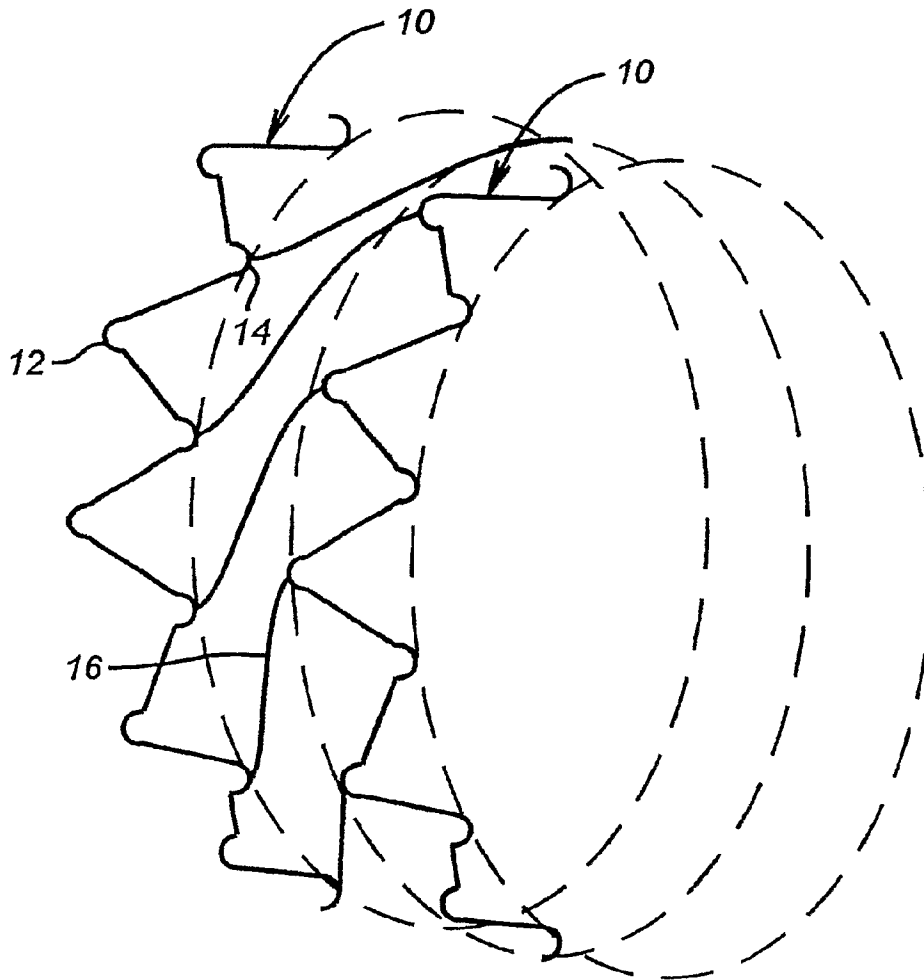


FIG. 11

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FLEXIBLE STENT

This application is a continuation of copending application Ser. No. 08/582,657, filed on Jan. 4, 1996.

FIELD OF THE INVENTION

The field of this invention relates to vascular stents that can be delivered to a predetermined position and allowed to spring outwardly or, in the alternative, which can be expanded in place.

BACKGROUND OF THE INVENTION

Vascular stents are structures that are designed to maintain the patency of a vessel in the body. The stent provides internal support to allow the circulation to proceed therethrough. Stents can be used in the vascular system in ureters, bile ducts, esophagus, and in many other tubular structures in the human body.

Stents can be tubular or can be made from wire. Stents are typically made from a metal or polymeric substance or a metal coated with polymers which are biocompatible or contain heparin to reduce blood clotting or other tissue reactions. Many prior designs have used a coil approach where a wire is helically wound on a mandrel. Yet other designs have evolved—braided wire mesh and angulated wire forms wrapped on a spindle to form a coil.

U.S. Pat. No. 5,292,331 by Boneau and U.S. Pat. No. 5,403,341 describe such wire forms. These devices have very poor radial support to withstand the hoop strengths of the artery or vein and further are not suitable for arteries that are bent or curved or for long lesions; multiple stents are required. These designs do not provide any support to hold the wall of the artery, other than the memory of the metal.

Wall Stent, produced by Pfizer Inc., is a braided wire tube. Although this stent is flexible so as to be placed in curved arteries or veins and other body cavities, it does not have any radial strength imparted to it by design.

Wiktor, U.S. Pat. No. 4,649,922; 4,886,062; 4,969,458; and 5,133,732 describe a wire form stent. He describes stents made of wire helix made of a preformed wire which is in the sinusoidal form, in which either all or some of the adjacent strands are connected.

Arthus Fontaine, U.S. Pat. No. 5,370,683, also describes a similar device where a flat wire form of sinusoidal shape is wound on a mandrel to form a helical coil. The wire bends are "U" shaped and are connected to alternate "U"-shaped bands.

Allen Tower, U.S. Pat. Nos. 5,217,483 and 5,389,106 describes a similar device where the wire is preformed to a sinusoidal shape and subsequently wound on a mandrel to form a helical coil.

All of the above-described art fails to provide radial support. The pre-shaped wire form (sinusoidal in most of the prior art) is wrapped on a mandrel to form a coil. However, the forces imported by the vessel wall's hoop strength are radially inward. In other words, the force is acting perpendicular to the plane of the U-shaped wire form. This means that the bends that are in the wire add no structural strength to the wire form to support the force produced by the wall, which is radially inward.

When we examine the simple coils, such as taught in Scott U.S. Pat. No. 5,383,928 or Gene Samson U.S. Pat. No. 5,370,691 or Rolando Gills U.S. Pat. No. 5,222,969, it is apparent that the spring coil will withstand substantial radial forces due to the vessel wall; however, all these stents are

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bulky in their pre-expanded form and are hard to place in small and curved arteries or veins of the body. Also, a major disadvantage of this design is that when the coil stent is placed in a curved artery or vein, it forms an "accordion" shape whereby some strands in the outer radius are spread and those of the inner radius are gathered. Spring coils can also "flip" to form a flat structure when a longitudinal force is applied on one side of the stent.

The other types of stents that have been developed are tube stents. Palmer, U.S. Pat. No. 4,733,665; 4,739,762; 7,776,337; and 4,793,348 describe such a tube stent of slotted metal tube. The slotted metal tube is expanded by a high-pressure balloon to implant the stent into the inside wall of the artery or vein.

Joseph Weinstein, U.S. Pat. No. 5,213,561 describes a similar stent made of tubular materials with slots cut into it. On expansion using a balloon, it forms a structure with diamond-shaped slots.

Henry Wall, U.S. Pat. No. 5,266,073 also describes a stent, tubular, that has slots machined into it. When expanded, the edges of the stent lock to form a cylinder. Not only is this device stiff and can only be used for short lesions, but also the diameter cannot be adjusted to meet the exact needs of the particular vessel but it is fixed to the predetermined sizes.

Lau and Hastigan, U.S. Pat. No. 5,344,426 describes a slotted tubular stent that has a structure similar to Henry Wall's but has provided prongs that will lock in as the stent is expanded.

Michael Marin, U.S. Pat. No. 5,397,355 also describes a tubular slotted stent with locking prongs.

U.S. Pat. No. 5,443,500 illustrates the use of square openings with rectangular prongs that stick therethrough to lock the stent. This design, as well as other locking mechanisms, generally have resulted in very stiff stents because of the use of a tubular-type grid construction. Further, the locking devices have resulted in sharp outwardly oriented tabs which are used for the locking, which could cause vascular damage.

All the above-described tube stents, although typically providing substantial radial support when expanded, are not flexible enough to be placed in curved vessels. Arteries and veins in the human body are mostly curved and are tapered. As such, these tube stents suffer from this main disadvantage.

European patent document 042172982 employs wires that are doubled up and whose ends are snipped off to make a given joint. Such doubling up at the junction of two elements with snipped off free ends creates a potential puncture problem upon radial expansion. The sheer bulk of the doubled up wires makes them rotate radially outwardly away from the longitudinal centerline of the stent, while the plain ends on such an arrangement which are snipped off offer the potential of sharp points which can puncture or damage the intima. On the other hand, the apparatus of the present invention, employing sharp angles, as defined, avoids this problem in an embodiment which illustrates a continuous wire or wire-like member bent into a sharp angle. This type of structure alleviates the concerns of sharp edges, as well as the tendency of a doubled up heavy joint to rotate outwardly toward the intima upon radial expansion of the stem, as would be expected in the EPO reference 042172982.

Often these stents are layered with polymeric sheaths that are impregnated with biocompatible substances or can be coated with heparin or hydrogel. Most sheath-type coatings

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reduce endothelial cell growth through the stent, which is a major requirement in successful stenting of body cavities such as arteries and veins.

Several parameters in design of stents are important. Of the more important parameters is the issue of recoil. Recoil deals with the memory of the stent material which, generally speaking, upon expansion in the blood vessel will want to recoil back to its original shape. This can be problematic because it is desirable for the stent, once expanded, to remain in good contact with the vessel wall to avoid longitudinal shifting. Furthermore, any recoil constricts the flow passage and presents a greater portion of the stent in the blood flowpath, thus creating additional complications due to the turbulence which ensues.

Related to the concern regarding recoil is another concern regarding component twist. This phenomenon generally occurs when the cross-sectional area of the components is rectangular, such as when the stent is manufactured from a cylindrical piece which is then cut by lasers or other means to form the particular pattern. Particularly in the honey-combed designs involving the use of square or rectangular element cross-sections, radial expansion of such stents generally results in a twist of the component segments such that they extend into the flowpath in the artery or vein. Again, this causes turbulence which is undesirable.

Related to the problem of recoil or constriction after expansion is the ability of the stent to anchor itself in the vascular wall. An anchoring system that does not cause trauma is a desirable feature not found in the prior art.

Yet other considerations which are desirable in a stent not found in the prior art is the flexibility to be maneuvered around bends in the vascular system, coupled with the ability to conform to a bend without kinking or leaving large open areas. The stents of the present invention have the objective of addressing the issue of recoil, as well as providing an anchoring mechanism to fixate the stent once set. Several of the designs incorporate flexibility to allow the stent to follow a bend or curve in a vascular flowpath while at the same time providing sufficient radial deformation to ensure proper fixation while minimizing angular twisting movements of the stent components to minimize turbulence through the stent.

In a recent article appearing in late 1995, by Dr. Donald S. Baim, entitled "New Stent Designs," a description is given of the ideal endovascular prosthesis. There, Dr. Baim indicates that the ideal stent should have low implantation profile with enhanced flexibility to facilitate delivery. He goes on to say that the stent should be constructed from a noncorrosive, nonthrombogenic radiopaque alloy and have expanded geometry which maximizes radial strength to resist vascular recoil. The ideal stent described by Baim is further described as having a wide range of diameters and lengths. Dr. Baim concludes that it is unlikely that any current designs satisfy all these requirements. Thus, one of the objectives of the present invention is to go further than the prior designs in satisfying the criteria for the ideal designs as set forth by Dr. Baim in his recent article.

SUMMARY OF THE INVENTION

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crosspieces that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual

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rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the stent of the present invention in an unrolled condition prior to expansion.

FIG. 2 is the stent shown in FIG. 1 in an unrolled condition after expansion.

FIG. 3 is a section along lines A—A of FIG. 1 and illustrates several different cross-sectional shapes that can be used for the stent illustrated in FIG. 1.

FIG. 4 is a detailed view of the stent in FIG. 1, shown without any cross-sectional changes to the undulating design of the ring structure illustrated in FIG. 1.

FIG. 5 is similar to FIG. 4 except that it employs singular notches adjacent reversing bends.

FIG. 6 employs a change in the cross-sectional shape taking place adjacent each reversing bend.

FIG. 7 illustrates a joint involving a transverse tab adjacent the reversing bends.

FIG. 8 involves opposed notches on each side of the wire adjacent a reversing bend.

FIG. 9 illustrates what occurs on radial expansion of each of the rings without the use of a stress-relief mechanism such as a notch or a cut-out.

FIG. 10 illustrates the action upon radial expansion using a notch and its effect on the reversing bend.

FIG. 11 is a perspective view of the stent shown in FIG. 2 in the expanded position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows, in flattened out form, a stent S which is unrolled along its longitudinal axis. The stent S has a series of rings 10 which are preferably of a wire material (preferably stainless steel, nickel-titanium alloys, tantalum alloys) bent in a series of reversing undulations 12 and 14. The wire can be coated with polymer such as polyethylene, polytetrafluoroethylene (Teflon®), or polylactates containing heparin or drugs or radioactive material. The bends 12 may have a similar radius or may vary as among bends 12 or as among bends 14. In other words, each of the bends 12 may be identical to each other. Each of the bends 14 may be identical to each other. Each bend 12 may be identical to each bend 14. One bend 12 can be different from another bend 12, which is in turn also different from another bend 14, or any combinations of the above. While rounded bends are shown as 12 and 14, other shapes can be used to create a generally undulating pattern, such as sharp bends which generally form a V-shape. Connecting each row 10 is one or more crosspieces 16. In the preferred embodiment, the crosspieces 16 have flexibility in that they have at least one bend 18, while a double bend, such as including 18 and 20, is preferred for the construction of the crosspieces 16. One or more crosspieces can be used which connect a bend 14 to its opposing bend 12. Thus, as shown in FIG. 1, the crosspieces 16, looking from bottom to top, make a bend to the left and a bend to the right on their way from reverse bend 12 to a reverse bend 14. One or more crosspieces 16 can be used between rings 10 up to a maximum where every reversing bend, such as 14, is connected to an adjacent but offset circumferentially reversing bend 12.

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FIG. 2 illustrates the stent S in a radially expanded form, illustrating that the crossties 16 continue to retain flexibility because of the reversing bends 18 and 20. Thus, the longitudinal flexibility of the stent S is retained, even in the expanded position. The use of the crossties with, at minimum, a single bend gives them flexibility. The design involving rings 10 connected by crossties 16 prevents stiffness experienced in some prior designs that had a particular longitudinal segment with undue stiffness giving the stent S a "backbone," thus making it unduly stiff longitudinally. Use of the flexible crossties 16 also provides flexibility for relative rotation between rings 10 while the expansion is taking place. Flexibility is also provided in the longitudinal direction as the crossties 16 may elongate in that direction without putting the stent S into a kink or a longitudinal bind.

FIG. 3 illustrates alternative cross-sectional shapes for the wire cross-section which makes up each of the rings 10 and/or the crossties 16. Thus, FIG. 3 illustrates squares, rectangles, circles, ovals, and composite shapes.

One of the concerns with an undulating structure, such as illustrated in FIG. 1, is the reversing bends 12 or 14, unless some provisions are made, experience undue stress and are even prone to bending out of their plane when the stent is radially expanded. This phenomenon is illustrated in FIG. 9. There, a pair of straight segments 22 and 24 are joined together by a reversing bend 26. As illustrated in FIG. 9, the cross-sectional area of the segments 22 and 24 are rectangular, one of the shapes shown in FIG. 3. It should be noted that other cross-sections, apart those illustrated in FIG. 3, can be used without departing from the spirit of the invention.

With no significant cross-sectional change occurring at the transition or near the transition 28 between the reverse bend 26 and the segments 24 or 22, the stress is transferred to the reverse bend 26 when an expansion force F tries to radially expand the stent S by moving segments 22 and 24 apart. Depending on the amount of stress induced, a bending occurs, as shown in FIG. 9, where the reverse bend 26 bends out of plane so that it is no longer in alignment with the segments 22 and 24, which was its condition prior to the application of force F.

FIG. 10 shows the contrast of the behavior of the reverse bend 26 when a notch 30 is placed adjacent the transition 28 between the reverse bend 26 and the segment 22 and a similar notch 32 is placed near transition 34 between the reverse bend 26 and the segment 24. What results is a reduced cross-sectional area at transitions 28 and 34. Thus, when force F is applied to the segments 22 and 24, there is a permanent bending occurring at the zone of least cross-sectional area, i.e., transitions 28 and 34, with their respective notches 30 and 32. Accordingly, the stress from radial expansion of a ring 10 as illustrated in FIG. 1 is absorbed by a bending or deformation at the transitions 28 and 32, thus minimizing if not eliminating the applied stress to the reverse bend 26 after radial expansion of the stent S by expanding all of the rings 10. This type of structure illustrated in FIG. 10 can be employed in the unrolled stent shown in FIGS. 1 and 2.

Other alternative mechanisms for reducing the stress at the reverse bend are illustrated in FIGS. 5-8. It should be noted that the features illustrated in FIGS. 5-8 are to be found in the stent shown in FIGS. 1 and 2; however, in order to show the overall layout of the stent S, FIGS. 1 and 2 are not sufficiently magnified so that these details can be seen. However, FIGS. 5-8 represent a greater magnification of adjacent reverse bends, such as 12 and 14.

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In FIG. 6, the connecting segments 36 and 38 have a smaller cross-sectional area than the cross-sectional area at the reverse bends 12 and 14, thus creating zones of transition of cross-section 40 adjacent reverse bend 14 and 42 adjacent reverse bend 12. This construction is typical for each of the rings 10 of a particular stent. It should be noted that the various features illustrated in FIGS. 5-8 can be used uniformly throughout the stent or mixed and matched for a desired effect.

The detail in FIG. 7 illustrates a cross-sectional area transition point 44 and 46, respectively adjacent reverse bends 12 and 14. Here, there is not only a transition cross-sectional area but transverse tabs 48 are used to secure the joint between segments 50 and 52, which have a smaller cross-sectional area than the cross-sectional area of reverse bends 12 and 14.

FIG. 8 illustrates the use of opposed notches 54 and 56 adjacent the entrance and exit to each reverse bend 12 and 14. FIG. 5 illustrates the use of similar notches 58 and 60 at the entrance and exit of each reverse bend 12 and 14. The difference between FIG. 5 and FIG. 8 is that in FIG. 8, the notches 54 and 56 oppose each other at the entrance and exit of each reverse bend 12 or 14, while in FIG. 5 the notches can be interiorly located, as shown in FIG. 5, or in the alternative, exteriorly located at the entrance and exit to each reverse bend 12 and 14. It should be noted that the changes in cross-sectional area do not need to be literally at the point of transition between the rounded portion of a reverse bend 12 or 14 and the straight segment which adjoins the reverse bends. However, the preferred location is at that transition. Locating the cross-sectional area change before entering the transition from the straight segment to the curved segment is also possible, depending on the degree of stress relief desired.

FIG. 11 illustrates the stent S shown in unrolled form in FIGS. 1 and 2 in a perspective view after radial expansion. It should be noted that the crossties 16 retain their flexibility, even after expansion, and that the reverse bends 12 and 14 have not buckled out of the cylindrical surface defined by the expanded stent S shown in FIG. 11. The buckling feature, which can occur in prior designs without the stress relief mechanism, is illustrated in FIG. 9.

FIG. 4 illustrates that it is within the purview of the invention to use a plurality of rings 10 connected by flexible crossties 16 without the change in cross-sectional area occurring at the reverse bends 12 and 14. While the embodiments in FIGS. 5-8 are preferred, it is within the purview of the invention to provide a stent with a multiplicity of rows 10 of undulating wire components which are connected by one or more crossties 16, each of which have at least one bend so that upon radial expansion into the position shown in FIGS. 2 and 11, the crossties 16 continue to retain flexibility in at least one but preferably more directions. Thus, the individual rings 10 have longitudinal flexibility and may rotate to some degree with respect to each other, all to conform to the tortuous path in which the stent S may be placed. By adding the change in the cross-sectional area feature, as shown in FIGS. 5-8, by using one or more of those features in a single stent, a stent is produced that is flexible, yet when expanded, retains its flexibility and is not subjected to stress to a significant degree at reversing bends after complete radial expansion. By focusing the stress occurring during radial expansion to a particular point outside the reversing bend, a simple-to-make construction occurs which addresses the concerns of some of the prior art designs which have tackled this problem by using varying degrees of curvature, such as European application No.

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0662307, assigned to Advanced Cardiovascular Systems. This design, with the flexible cross-ties 16, represents a considerably more flexible design than rolled up coil springs such as that illustrated in U.S. Pat. No. 4,969,458. Cross-ties which are essentially straight, such as those illustrated in U.S. Pat. No. 5,421,955, do not afford the flexibility realized by the stent S of the present invention. It should be noted that as more bulk is presented at the transition between segments such as 22 and 24 in FIG. 9, the more likely is the bending to occur when subjected to radial expansion, as illustrated schematically by force F. Thus, designs that use doubled up wires at the apex, such as European application No. 0421729, assigned to Medtronic, exacerbate the bending results shown in FIG. 9, as well as increasing the stiffness of the stent and the force necessary for radial expansion of each of its individual rings. Additionally, by use of cross-ties which are coiled springs which protrude out of the cylindrical surface defined by the stent S, additional complications are created since the cross-ties will intrude into the vascular wall, creating additional irritation to the patient or worse damage if there is penetration of the vascular wall.

Accordingly, the above-described stent S of the present invention has the advantages of flexibility in view of the unique cross-ties which are used. The cross-ties remain in the cylindrical surface defined by the shape of the stent S, even upon radial expansion. The cross-ties 16 retain their flexibility, even after full radial expansion occurs. By use of the cross-sectional area changes, the applied stresses from radial expansion are focused to this transition zone as opposed to other places, such as the return bends. By focusing the deformation to the transition zone, stress is minimized or reduced in the reverse bend section, such as 12 or 14, and further the tendency of the reverse bends such as 12 or 14 to protrude out of the cylindrical surface defined by the stent S is greatly reduced, if not eliminated.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

What is claimed is:

1. A stent comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends and at least two cross-sectional areas identified by at least one cross-sectional change location, said wire member forming an undulating pattern;

at least one cross-tie connecting adjacent rings said cross-tie disposed in general alignment with a longitudinal axis defined by said rings, said cross-tie having at least one bend formed therein;

the cross-sectional area of said wire member changes adjacent at least one of said reversing bends;

said wire member which comprises each said rings, when expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends; and

said reversing bends remain generally aligned to said cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

2. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular

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elongated wire member having discrete reversing bends which do not intersect with other reversing bends, and at least two cross-sectional areas defined by at least one cross-sectional change location, said wire member forming an undulating pattern;

at least one cross-tie connecting adjacent rings said cross-tie disposed in general alignment with a longitudinal axis defined by said rings, said cross-tie having at least one bend formed therein;

said wire member having at least one straight section between said reversing bends;

the cross sectional area of said wire member changes in said straight section and adjacent said reversing bends;

said wire member which comprises each said rings, when expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends; and

said reversing bends remain generally aligned to said cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

3. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends, said wire member forming an undulating pattern, said wire member having at least one cross-sectional area;

at least one cross-tie connecting adjacent rings said cross-tie disposed in general alignment with a longitudinal axis defined by said rings, said cross-tie having at least one bend formed therein;

the wire member is formed having a notch wherein the cross-sectional area of the wire member changes at a notch location;

said notch is located adjacent at least one of said reversing bends.

4. The stent of claim 3, wherein:

said change in cross-section is accomplished by opposed notches.

5. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having reversing bends forming an undulating pattern;

at least one cross-tie connecting adjacent rings wherein said cross-tie is disposed in general alignment with a longitudinal axis defined by said rings; and

said wire member is formed having a notch adjacent at least one of said reversing bends which defines a change in cross-sectional area.

6. The stent of claim 5, wherein:

said change in cross-sectional area is accomplished by opposed notches.

7. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing

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bends, said wire member forming an undulating pattern; and having at least two cross-sectional areas identified by at least one cross-sectional change location; and

at least one cross-tie having said connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed between said ends to allow said crosstie to flex as said rings expand while remaining within the confines of said cylindrical shape; and

the cross-sectional area of said wire member changes adjacent at least one of said reversing bends.

8. The stent of claim 7, wherein:

said wire member changes cross-section adjacent each said reversing bend.

9. The stent of claim 8, wherein:

said wire member changes cross-section on both sides of each said reversing bend.

10. The stent of claim 7, wherein:

said wire member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

11. The stent of claim 1, further comprising:

a plurality of non-overlapping crossties each having at least two bends.

12. The stent of claim 11, wherein:

said bends define at least two slope changes in said crossties.

13. The stent of claim 12, wherein:

each crosstie connects a reversing bend in one of said rings to the next adjacent circumferentially offset reversing bend on an adjacent ring.

14. The stent of claim 1, wherein:

said at least one crosstie comprises at least two reversing bends located remotely from said end of said crosstie.

15. The stent of claim 7 wherein:

said at least one crosstie comprises at least two reversing bends located remotely from said ends of said crosstie; and

said bends define a turn of no less than about 90°.

16. The stent of claim 15, wherein:

said crosstie having a first end offset circumferentially from a second end.

17. The stent of claim 15, wherein that portion of said crossties extending between said first and second ends and up to said bends of said crosstie are in substantial longitudinal alignment with the longitudinal axis of said cylindrical shape.

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18. The stent of claim 3, wherein:

said wire-like member has straight sections between said reversing bends;

said straight sections have a smaller cross-sectional area than the cross-sectional area through said reversing bends.

19. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends; said wire member forming an undulating pattern and having at least one cross-section;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein; and

said wire member having at least one straight section between said reversing bends;

the cross-section of said wire member changes in said straight section and adjacent said reversing bends.

20. The stent of claim 9, wherein:

said straight section has a smaller cross-sectional area than the cross-sectional area through an adjacent said reverse bend.

21. The stent of claim 19, wherein:

said wire member changes cross-section adjacent each said reversing bend.

22. The stent of claim 19, wherein:

said wire member changes cross-section on both sides of each said reversing bend.

23. The stent of claim 19, wherein:

said wire member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

24. A stent of claim 19, further comprising:

a plurality of non-overlapping crossties each having at least two bends.

25. The stent of claim 24, wherein:

said bends define at least two slope changes in said crossties.

26. The stent of claim 25, wherein:

each crosstie connects a reversing bend in one of said rings to the next adjacent circumferentially offset reversing bend on an adjacent ring.

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